Medicines & Healthcare products Regulatory Agency

Public Assessment Report

Decentralised Procedure

Sondate/Quelento/Sarparm XL 50 mg Prolonged-release Tablets
Sondate/Quelento/Sarparm XL 200 mg Prolonged-release Tablets
Sondate/Quelento/Sarparm XL 300 mg Prolonged-release Tablets
Sondate/Quelento/Sarparm XL 400 mg Prolonged-release Tablets

(Quetiapine fumarate)

Procedure Nos: UK/H/2074 and UK/H/4674-5/01-4/DC

UK Licence No: PL 00289/1219-22 and PL 00289/1506-13

Teva UK Limited

LAY SUMMARY

Sondate/Quelento/Sarparm XL 50 mg Prolonged-release Tablets
Sondate/Quelento/Sarparm XL 200 mg Prolonged-release Tablets
Sondate/Quelento/Sarparm XL 300 mg Prolonged-release Tablets
Sondate/Quelento/Sarparm XL 400 mg Prolonged-release Tablets

(Quetiapine fumarate)

This is a summary of the Public Assessment Report (PAR) for Sondate/Quelento/Sarparm XL 50, 200, 300 and 400 mg Prolonged-release Tablets (PL 00289/1219-22 and PL 00289/1506-13; UK/H/2074/01-4/DC and UK/H/4674-5/01-4/DC). It explains how Sondate/Quelento/Sarparm XL 50, 200, 300 and 400 mg Prolonged-release Tablets were assessed and their authorisation recommended as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Sondate/Quelento/Sarparm Tablets in this lay summary for ease of reading.

For practical information about using Sondate/Quelento/Sarparm Tablets, patients should read the package leaflets or contact their doctor or pharmacist.

What is Sondate/Quelento/Sarparm Tablets and what are they used for?
Sondate/Quelento/Sarparm Tablets are 'generic medicines'. This means that they are similar to the 'reference medicines', already authorised in the UK called Seroquel XL 50, 200, 300 and 400 mg prolonged-released tablets (AstraZeneca UK Limited, UK).

Sondate/Quelento/Sarparm Tablets are used to treat several illnesses, such as:

- Bipolar depression and major depressive episodes in major depressive disorder: where patients feel sad. They may find that they feel depressed, feel guilty, lack energy, lose their appetite or can't sleep
- Mania: where patients may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgement including being aggressive or disruptive.
- Schizophrenia: where patietns may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty tense or depressed.

How do Sondate/Quelento/Sarparm Tablets work?
Sondate/Quelento/Sarparm Tablets contains the active ingredient quetiapine, which belongs to a group of medicines called anti-psychotics. This medicine affects the action of a number of chemicals in the brain called neurotransmitters – chemicals which brain cells need to communicate with each other.

How are Sondate/Quelento/Sarparm Tablets used?
Sondate/Quelento/Sarparm Tablets are taken by mouth. The tablet should be swallowed whole with a drink of water. The tablet should not be split, chewed or crushed. This medicine must be taken without food (at least one hour before a meal or at bedtime).

The maintenance dose (daily dose) will depend on patient's illness and needs but will usually be between 150 mg and 800 mg. Patients should not drink grapefruit juice while they are taking this medicine as it can affect the way it works.

The dose in elderly people or patients with liver problems may be changed by a doctor

Sondate/Quelento/Sarparm Tablets should not be used by children and adolescents aged under 18 years.

This medicine can only be obtained with a prescription.

Please read Section 3 of the patient information leaflet for detailed information on dosing recommendations, the route of administration and the duration of treatment.

How have Sondate/Quelento/Sarparm Tablets been studied?
Because Sondate/Quelento/Sarparm Tablets are generic medicines, studies in patients have been limited to tests to determine that they are bioequivalent to the reference medicines, Seroquel XL 50, 200, 300 and 400 mg prolonged-released tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Sondate/Quelento/Sarparm Tablets?
Because Sondate/Quelento/Sarparm Tablets are generic medicines, and are bioequivalent to the reference medicines, Seroquel XL 50, 200, 300 and 400 mg prolonged-released tablets, their benefits and risks are taken as being the same as the reference medicines.

Why is Sondate/Quelento/Sarparm Tablets approved?
It was concluded that, in accordance with EU requirements, Sondate/Quelento/Sarparm Tablets have been shown to have comparable quality and to be bioequivalent to Seroquel XL 50, 200, 300 and 400 mg prolonged-released tablets. Therefore, the view was that, as for Seroquel XL 50, 200, 300 and 400 mg prolonged-released tablets, the benefits outweigh the identified risks.

What measures are being taken to ensure the safe and effective use of Sondate/Quelento/Sarparm Tablets?
A risk management plan has been developed to ensure that Sondate/Quelento/Sarparm Tablets are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPC) and the package leaflet for Sondate/Quelento/Sarparm Tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients and healthcare professionals will be monitored and reviewed continuously as well.

Other information about Sondate/Quelento/Sarparm Tablets
Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Slovak Republic, Spain and the UK agreed to grant Marketing Authorisations for Sondate/Quelento/Sarparm Tablets on 23 November 2011. Marketing Authorisations were granted in the UK on 22 December 2011.

The name of the product was changed from Sondate XL 50, 200, 300 and 400 mg Prolonged-release Tablets to Quelento XL 50, 200, 300 and 400 mg Prolonged-release Tablets (PL 00289/1506-9; UK/H/4674/001-4/DC) and to Sarparm XL 50 mg Prolonged-release Tablets (PL 00289/1510-13; UK/H/4675/001-4/DC) via variations that were approved on 22 January 2013.

The full PAR for Sondate/Quelento/Sarparm Tablets follows this summary.

This summary was last updated in January 2018.

SCIENTIFIC DISCUSSION

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the member states considered that the applications for Sondate XL 50 mg, 200 mg, 300 mg and 400 mg prolonged-release tablets (PL 00289/1219-22 and PL 00289/1506-13; UK/H/2074 and UK/H/4674-5/01-4/DC) could be approved. The products are prescription-only medicines (POM) indicated for the treatment of:

- schizophrenia,
- bipolar disorder including:
  - moderate to severe manic episodes in bipolar disorder
  - major depressive episodes in bipolar disorder
  - preventing recurrence in bipolar disorder in patients whose manic or depressive episode has responded to quetiapine treatment.

Sondate XL 50 mg, 200 mg, 300 mg and 400 mg prolonged-release tablets are also indicated as add-on treatment of major depressive episodes in patients with Major Depressive Disorder (MDD) who have had sub-optimal response to antidepressant monotherapy. Prior to initiating treatment, clinicians should consider the safety profile of quetiapine.

These applications were submitted using the Decentralised Procedure (DCP), with the UK as Reference Member State (RMS), and Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Slovak Republic and Spain as Concerned Member States (CMS). These applications were submitted under Article 10(1) of Directive 2001/83/EC, as amended, as generic applications. The reference medicinal product for these applications is Seroquel 200 mg film-coated tablets (AstraZeneca BV, Netherlands), which was first authorised in the Netherlands on 27 April 1998. Reference is also made to the corresponding prolonged-release UK reference products Seroquel XL 50 mg, 200 mg, 300 mg and 400 mg prolonged-released tablets (AstraZeneca UK Limited, UK), which were first authorised in the UK on 10 September 2008.

Sondate XL 50mg, 200 mg, 300 mg and 400 mg prolonged-release tablets contain the active ingredient quetiapine (as quetiapine fumarate), which is an atypical antipsychotic.

No new non-clinical data have been submitted, which is acceptable given that the applications were based on being generic medicinal products of originator products that have been in clinical use for over 10 years.

Eight (four single-dose and four multiple-dose) bioequivalence studies were submitted to support these applications, comparing the test products Quetiapine Prolonged Release (PR) 50 mg, 200 mg, 300 mg and 400 mg Tablets with the corresponding reference products Seroquel XR 50 mg, 200 mg, 300 mg and 400 mg Tablets (AstraZeneca BV, Netherlands), and Seroquel Prolong 200 mg Retardtabletten (AstraZeneca GmbH, Germany). During product development, Quetipine PR was the name used for the Sondate XL products. The bioequivalence studies were carried out in accordance with Good Clinical Practice (GCP).

With the exception of the bioequivalence studies, no new clinical data were submitted, which is acceptable given that the applications were based on being generic medicinal products of an originator product that have been in clinical use for over 10 years. The bioequivalence studies were carried out in accordance with Good Clinical Practice (GCP).

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place at all sites responsible for the manufacture, assembly and batch release of these products. For

manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

The RMS and CMS considered that the applications could be approved at the end of procedure (Day 210) on 23 November 2011. After a subsequent national phase, licences were granted in the UK on 22 December 2011.

The name of the product was changed from Sondate XL 50, 200, 300 and 400 mg Prolonged-release Tablets to Quelento XL 50, 200, 300 and 400 mg Prolonged-release Tablets (PL 00289/1506-9; UK/H/4674/001-4/DC) and to Sarparm XL 50, 200, 300 and 400 mg Prolonged-release Tablets (PL 00289/1510-13; UK/H/4675/001-4/DC) via variations that were approved on 22 January 2013.

II QUALITY ASPECTS

II.1 Introduction

The products are presented as prolonged-release tablets. Each tablet contains 50, 200, 300 and 400 mg quetiapine (as quetiapine fumarate).

Other ingredients consist of the pharmaceutical excipients in the tablet core and film coating, namely hypromellose, cellulose microcrystalline, sodium citrate anhydrous, magnesium stearate, titanium dioxide (E171), macrogol/PEG 400, Polysorbate 80. The 50 mg, 200, mg and 300mg strength tablets also contain yellow iron oxide (E172) and red iron oxide (E172) and the 50 mg and 300 mg strength tablets also contain black iron oxide (E172). Appropriate justifications for the inclusion of each excipient have been provided.

All excipients comply with their respective European Pharmacopoeia monograph, with the exception of sodium citrate anhydrous, yellow iron oxide (E172), red iron oxide (E172) and black iron oxide (E172). Sodium citrate anhydrous is controlled to a suitable in-house specification. Iron oxide yellow (E172), iron oxide red (E172) and iron oxide black (E172) are controlled to National Formulary specifications and are in compliance with current EU Directives concerning the use of colouring agents. Satisfactory Certificates of Analysis have been provided for all excipients.

None of the excipients contain materials of animal or human origin. No genetically modified organisms (GMO) have been used in the preparation of these excipients.

The tablets are packaged in either:

1. polyvinylchloride/Aclar/Aluminium (PVC/Aclar/Al) blisters, in pack sizes of 10, 20, 30, 50, 50x1 (hospital pack), 56 (calendar pack), 60, 90 and 100 prolonged-release tablets.
2. white opaque high-density polyethylene (HDPE) bottles, with white opaque polypropylene (PP) screw caps containing dessicant, in a pack size of 60 prolonged-release tablets.

Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

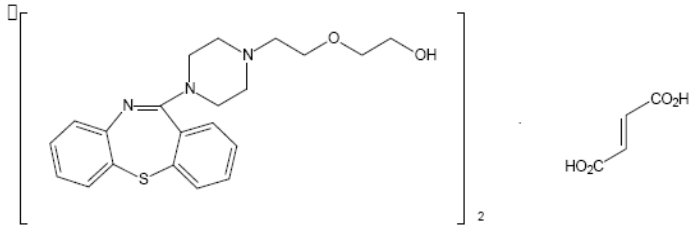
II.2 Drug substance

INN: Quetiapine fumarate

Chemical Name: Bis [2-(2-[4-(dibenzo[b,f][1,4]thiapin-11-yl) piperazin-1-yl] ethoxy)ethanol], fumarate;
Ethanol [2-(2-[4-(dibenzo[b,f][1,4]-thiazepin-11-yl-1)piperazinyl)ethoxy]-(E)-2-butenedionate (2:1)

Molecular formula: $(C_{21}H_{25}N_3O_2S)_2.C_4H_4O_4$

Structure:



Molecular mass: 883.10 g/mol

Appearance: A white to off-white crystalline powder, moderately soluble in water, freely soluble in acetic acid and slightly soluble in methanol and ethanol.

Quetiapine fumarate is not the subject of a European Pharmacopoeia monograph.

Synthesis of the active substance from the designated starting materials has been adequately described, and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant Certificates of Analysis.

Appropriate proof-of-structure data have been supplied. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the specification limits. Batch analysis data are provided and comply with the proposed specification.

Satisfactory Certificates of Analysis have been provided for all working standards.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with foodstuff.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3 Medicinal Product

Pharmaceutical Development

The objective of the development programme was to formulate safe, efficacious, stable prolonged-release tablets containing 50 mg, 200 mg, 300 mg and 400 mg quetiapine that could be considered generic medicinal products of Seroquel XL 50 mg, 200 mg, 300 mg, and 400 mg prolonged-release tablets (AstraZeneca UK Limited, UK). Suitable pharmaceutical development data have been provided for these applications.

Suitable pharmaceutical development data have been provided for these applications.

Comparative *in-vitro* dissolution and impurity profiles have been provided for these products and their respective reference products.

Manufacture of the products

Satisfactory batch formulae have been provided for the manufacture of all strengths of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated at production scale and has shown satisfactory results.

Finished Product Specifications

The finished product specifications are satisfactory. The test methods have been described and adequately validated, as appropriate. Batch data have been provided and comply with the release specifications. Certificates of Analysis have been provided for any working standards used.

Stability of the products

Finished product stability studies were performed in accordance with current guidelines on batches of

finished product packed in the packaging proposed for marketing. The data from these studies support a shelf-life of 2 years, with no special storage conditions. After first opening the HDPE bottle/container, the product should be used within 60 days.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

Bioequivalence/bioavailability
Satisfactory Certificates of Analysis have been provided for the test and reference batches used in the bioequivalence studies. The bioequivalence studies are discussed in Section III.3, Clinical Aspects.

II.4 Discussion on chemical, pharmaceutical and biological aspects
There are no objections to the approval of these products from a pharmaceutical viewpoint.

III NON-CLINICAL ASPECTS
III.1 Introduction
The pharmacodynamic, pharmacokinetic and toxicological properties of quetiapine fumarate are well known. No new non-clinical data have been submitted for these applications and none are required.

The applicant has provided an overview based on published literature. The non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

III.2 Pharmacology
Not applicable, see Section III.1 Introduction, above.

III.3 Pharmacokinetics
Not applicable, see Section III.1 Introduction, above.

III.4 Toxicology
Not applicable, see Section III.1 Introduction, above.

III.5 Ecotoxicity/Environmental Risk Assessment (ERA)
Suitable justification has been provided for not submitting an Environmental Risk Assessment. As the products are intended for generic substitution with products that are already marketed, no increase in environmental exposure to quetiapine is anticipated. Thus, the justification for not submitting an Environmental Risk Assessment is accepted.

III.6 Discussion of the non-clinical aspects
There are no objections to the approval of these products from a non-clinical viewpoint.

IV CLINICAL ASPECTS
IV.1 Introduction
The clinical pharmacology of quetiapine fumarate is well-known. With the exception of data from the bioequivalence studies detailed below, no new pharmacodynamics or pharmacokinetic data are provided or are required for this type of applications.

No new efficacy or safety studies have been performed and none are required for this type of applications. A comprehensive review of the published literature has been provided by the Applicant, citing the well-established clinical pharmacology, efficacy and safety of quetiapine fumarate.

IV.2 Pharmacokinetics

In support of the applications, the Marketing Authorisation Holder initially submitted the following six bioequivalence studies:

Study 1

A randomised, open label, single-dose, three-period, three-sequence, two-treatment, partial replicate, crossover study comparing the pharmacokinetics of the test product A, Quetiapine PR 50 mg Tablets and the reference product B, Seroquel XR 50 mg Tablets (AstraZeneca BV, Netherlands) in healthy adult male and female subjects under fasting conditions.

The subjects were given a single dose of either treatment with 240ml of water after at least a 10-hour overnight fast. The reference product B tablet was administered twice (replicate trial design) and hence each subject was randomised to one of three dosing sequences: ABB, BAB or BBA. Blood samples were collected before and up to 36 hours after each administration. The washout period between the treatment periods was 7 days. The pharmacokinetic results are presented below:

Pharmacokinetic parameters (geometric means, ratios and confidence intervals [CI]) of quetiapine)

Parameters (Units)	**Ln-transformed Geometric Means and its Ratio**			**90% Confidence Interval (ln-transformed)**	**CV (%)**
	Quetiapine PR 50 mg (Test)	**Seroquel XR 50 mg (Reference)**	**Test/Ref Ratio (%)**		
AUC_{0-t} (ng h/mL)	591.50	609.04	97.12	92.14-102.37	
C_{max} (ng/mL)	43.43	44.67	97.22	90.04-104.98	24

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
CV coefficient of variation
Ratios and 90% CI calculated from log-transformed data

The 90% confidence intervals of the test/reference ratio for $AUC_{0-t,}$ and C_{max} lie within the acceptable limits of 80% to 125%, in line with the '*Note for Guidance on the Investigation of Bioavailability and* Bioequivalence (CPMP/EWP/QWP/1401/98). Thus, the data support the claim that the test product Quetiapine PR 50 mg Tablets is bioequivalent to the reference product Seroquel XR 50 mg Tablets (AstraZeneca BV, Netherlands) in healthy subjects after a single oral dose, under fasting conditions.

Study 2

A randomised, open label, single-dose, three-period, three-sequence, two-treatment, partial replicate, crossover study comparing the pharmacokinetics of the test product A, Quetiapine PR 50 mg Tablets and the reference product B, Seroquel XR 50 mg Tablets (AstraZeneca BV, Netherlands), in healthy adult male and female subjects under fed conditions.

The subjects were given a single dose of either treatment with 240ml of water after a high fat, high calorie breakfast after an overnight fast. The reference B tablet was administered twice (replicate trial design) and hence each subject was randomised to one of three dosing sequences: ABB, BAB or BBA. Blood samples were collected before and up to 36 hours after each administration. The washout period between the treatment periods was 7 days. The pharmacokinetic results are presented below:

Pharmacokinetic parameters (geometric means, ratios and confidence intervals [CI]) of quetiapine)

Parameters (Units)	**Ln-transformed Geometric Means and its Ratio**			**90% Confidence Interval (ln-transformed)**	**CV (%)**
	Quetiapine PR 50 mg (Test)	**Seroquel XR 50 mg (Reference)**	**Test/Ref Ratio (%)**		
AUC_{0-t} (ng h/mL)	568.15	562.89	100.93	97.50-104.49	
C_{max} (ng/mL)	87.13	85.51	101.89	96.00-108.15	21

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
CV coefficient of variation
Ratios and 90% CI calculated from log-transformed data

The 90% confidence intervals of the test/reference ratio for AUC_{0-t}, and C_{max} lie within the acceptable limits. Thus, the data support the claim that the test product Quetiapine PR 50 mg Tablets is bioequivalent to the reference product Seroquel XR 50 mg Tablets (AstraZeneca BV, Netherlands) in healthy subjects after a single oral dose, under fed conditions.

Study 3
A randomised, open label, multiple-dose, three-period, three-sequence, two-treatment, partial replicate, crossover study comparing the pharmacokinetics of the test product A, Quetiapine PR 50 mg Tablets and the reference product B, Seroquel XR 50 mg Tablets (AstraZeneca BV, Netherlands) in healthy adult male and female subjects under fasting conditions.

The subjects were given a single dose of either treatment with 240ml of water after an overnight fast. The study drugs were administered once daily for 13 days over three treatment periods (period 1 – Days 1 to 5, period 2 - Days 6 to 9, and period 3 - Days 10 to 13). The reference B tablet was administered twice (replicate trial design), hence each subject was randomised to one of three dosing sequences: ABB, BAB or BBA. There was no washout period between the treatment periods. The elimination half-life of quetiapine is approximately 7 hours. It can therefore be assumed that steady state would be reached in each of the three study periods and that there would be no significant carryover of drug from one period into the sampling phase of the subsequent period.
Blood samples were collected before each administration on Days 1, 3, 4, 7, 8, 11 and 12, and before and up to 24 hours after each administration on Days 5, 9 and 13. The pharmacokinetic results are presented below:

Pharmacokinetic parameters (geometric means, ratios and confidence intervals [CI]) of quetiapine)

Parameters (Units)	Ln-transformed Geometric Means and its Ratio			90% Confidence Interval (ln-transformed)	CV (%)
	Quetiapine PR 50 mg (Test)	Seroquel XR 50 mg (Reference)	Test/Ref Ratio (%)		
AUC_{0-tau} (ng h/mL)	581.71	561.21	103.65	100.16-107.27	
C_{max} (ng/mL)	49.38	47.56	103.85	97.63-110.46	18
C_{trough} (ng/ml)	8.41	8.32	101.04	91.40-111.69	

AUC_{0-tau} area under the plasma concentration-time during a dosage interval in steady state
C_{max} maximum plasma concentration over a dosing interval
C_{trough} plasma concentration at the end of the dosing interval
CV coefficient of variation
Ratios and 90% CI calculated from log-transformed data

The 90% confidence intervals of the test/reference ratio for AUC_{0-tau}, C_{max}, and C_{trough} lie within the acceptable limits. Thus, the data support the claim that the test product Quetiapine PR 50 mg Tablets is bioequivalent to the reference product Seroquel XR 50 mg Tablets (AstraZeneca BV, Netherlands) at steady state in healthy subjects after multiple, oral doses, under fasting conditions.

Study 4

A randomised, open label, single-dose, three-period, three-sequence, two-treatment, partial replicate, crossover study comparing the pharmacokinetics of the test product A, Quetiapine PR 200 mg Tablets and the reference product B, Seroquel XR 200 mg Tablets (AstraZeneca BV, Netherlands) in healthy adult male and female subjects under fasting conditions.

The subjects were given a single dose of either treatment with 240ml of water after at least a 10-hour overnight fast. The reference B tablet was administered twice (replicate trial design) and hence each subject was randomised to one of three dosing sequences: ABB, BAB or BBA. Blood samples were collected before and up to 48 hours after each administration. The washout period between the treatment periods was 7 days. The pharmacokinetic results are presented below:

Pharmacokinetic parameters (geometric means, ratios and confidence intervals [CI]) of quetiapine)

Parameters(Units)	Ln-transformed Geometric Means and its Ratio			90% Confidence Interval (ln-transformed)	CV (%)
	Quetiapine PR 200 mg (Test)	Seroquel XR 200 mg (Reference)	Test/Ref Ratio (%)		
AUC_{0-t} (ng h/mL)	2400.90	2371.88	101.22	95.05-107.8	
C_{max} (ng/mL)	212.70	189.85	112.04	103.76-120.97	31

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
CV coefficient of variation
Ratios and 90% CI calculated from log-transformed data

The 90% confidence intervals of the test/reference ratio for $AUC_{0-t,}$ and C_{max} lie within the acceptable limits. Thus, the data support the claim that the test product Quetipine PR 200 mg Tablets is bioequivalent to the reference product Seroquel XR 200 mg Tablets (AstraZeneca BV, Netherlands) in healthy subjects after a single, oral dose, under fasting conditions.

The results demonstrate that the intra-subject coefficient of variation of C_{max} for the reference product was greater than 30%. However, as the 90% confidence intervals of the test/reference ratio for AUC_{0-t} and C_{max} lie within the defined limits of 80 to 125%, the proposed widening of the acceptance criteria was not necessary.

Study 5

A randomised, open label, single-dose, three-period, three-sequence, two-treatment, partial replicate, crossover study comparing the pharmacokinetics of the test product A, Quetiapine PR 200 mg Tablets and the reference product B, Seroquel XR 200 mg Tablets (AstraZeneca BV, Netherlands) in healthy adult male and female subjects under fed conditions.

The subjects were given a single dose of either treatment with 240ml of water after a high fat, high calorie breakfast after an overnight fast. The reference B tablet was administered twice (replicate trial design) and hence each subject was randomised to one of three dosing sequences: ABB, BAB or BBA. Blood samples were collected before and up to 48 hours after each administration. The washout period between the treatment periods was 7 days. The pharmacokinetic results are presented below:

Pharmacokinetic parameters (geometric means, ratios and confidence intervals [CI]) of quetiapine)

Parameters(Units)	**Ln-transformed Geometric Means and its Ratio**			**90% Confidence Interval (ln-transformed)**	**CV (%)**
	Quetiapine PR 200 mg (Test)	**Seroquel XR 200 mg (Reference)**	**Test/Ref Ratio (%)**		
AUC_{0-t} (ng h/mL)	2370.12	2341.92	101.20	97.40-105.16	
C_{max} (ng/mL)	387.84	333.71	116.22	108.41-124.60	25

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
CV coefficient of variation
Ratios and 90% CI calculated from log-transformed data

The 90% confidence intervals of the test/reference ratio for AUC_{0-t} and C_{max} lie within the acceptable limits. Thus, the data support the claim that the test product Quetiapine PR 200 mg Tablets (Teva Pharmaceutical Works Private Limited Company, Hungary) is bioequivalent to the reference product Seroquel XR 200 mg Tablets (AstraZeneca BV, Netherlands) in healthy subjects after a single, oral dose, under fed conditions.

Study 6

A randomised, open label, multiple dose, two-treatment, three-period, three-sequence, partial replicate crossover study comparing the pharmacokinetics of the test product A, Quetiapine PR 400mg Tablets and the reference product B, Seroquel XR 400mg tablets (AstraZeneca BV, Netherlands), in male and female subjects with primary psychotic and/or bipolar disorder, under fasting conditions.

The subjects were given 400 mg of either treatment with 240ml of water after an overnight fast. The study drugs were administered once daily for 13 days over three treatment periods (period 1 - Days 1 to 5, period 2 - Days 6 to 9, and period 3 - Days 10 to 13). The reference B tablet was administered twice (replicate trial design), hence each subject was randomised to one of three dosing sequences: ABB, BAB or BBA. There was no washout period between the treatment periods. The elimination half life of quetiapine is approximately 7 hours. It can therefore be assumed that steady state would be reached in each of the three study periods and that there would be no significant carryover of drug from one period into the sampling phase of the subsequent period. Blood samples were collected before each administration on days 1, 3, 4, 7, 8, 11 and 12, and before and up to 24 hours after each administration on Days 5, 9 and 13. The pharmacokinetic results are presented below:

Pharmacokinetic parameters (geometric means, ratios and confidence intervals [CI]) of quetiapine)

Parameters (Units)	**Ln-transformed Geometric Means and its Ratio**			**90% Confidence Interval (ln-transformed)**	**CV (%)**
	Quetiapine PR 400 mg (Test)	**Seroquel XR 400 mg (Reference)**	**Test/Ref Ratio (%)**		
$AUC_{0\text{-}tau}$ (ng h/mL)	4603.58	4654.68	98.90	94.44-103.57	
C_{max} (ng/mL)	440.08	446.31	98.60	91.54-106.21	23
C_{trough} (ng/mL)	57.69	64.17	89.90	80.59-100.28	36

$AUC_{0\text{-}tau}$ area under the plasma concentration-time curve during a dosage interval at steady state
C_{max} maximum plasma concentration over a dosing interval
C_{trough} plasma concentration at the end of the dosing interval
CV coefficient of variation
Ratios and 90% CI calculated from log-transformed data

The 90% confidence intervals of the test/reference ratio for $AUC_{0\text{-}tau}$, C_{max} and C_{trough} lie within the acceptable limits. Thus, the data support the claim that the test product Quetiapine PR 400 mg Tablets is bioequivalent to the reference product Seroquel XR 400 mg Tablets (AstraZeneca BV, Netherlands) at steady state in subjects with primary psychotic and/or bipolar disorder, after multiple doses, under fasting conditions.

In response to requests by the RMS and CMS, the applicant submitted the following two additional bioequivalence studies to support the applications:

Study 7:
A randomised, open label, multiple-dose, two-treatment, two-period, two-way, crossover study comparing the pharmacokinetics of the test product A, Quetiapine PR 200mg Tablets and the reference product B, Seroquel Prolong 200 mg Retardtabletten (AstraZeneca GmbH, Germany) in healthy adult male and female subjects under fasting conditions.

The study included 3 phases:

- ***Titration***: step-up increase of quetiapine doses from 50mg to 150mg over 3 days (Day -2 to 0)
- ***Period 1***: building the steady-state and pharmacokinetic sampling (Day 1 to 5)
- ***Period 2***: switch to the alternate treatment, maintain the steady-state and collect pharmacokinetic samples (Day 6 to 9)

In order to reduce the adverse events, over a period of 4 days the subjects received increasing doses of

quetiapine starting with 50 mg up to the 200 mg dose which was the strength of the tested formulations. The 50mg product used was Seroquel XR 50 mg Tablets from the Canadian market. The use of a non-EU product is acceptable in this context (initial dose titration) as, based on the elimination half-life of about 7 hours it would be making a negligible contribution to the blood levels by Day 5 of the study (first sampling day).

The subjects were given a single dose of either the test or reference product with 100 mL of water after an overnight fast. Subjects were randomly assigned to one of the two dosing sequences AB or BA under fasting conditions. Blood samples were collected over a 24-hour interval on Days 5 and 9, and in pre-doses on Days 2, 3, 4, 5, 7, 8 and 9. There was no washout period between the treatment periods. The pharmacokinetic results are presented below:

Pharmacokinetic parameters (geometric means, ratios and confidence intervals [CI]) of quetiapine

Parameters(Units)	**Ln-transformed Geometric Means and its Ratio**			**90% Confidence Interval (ln-transformed)**	**CV (%)**
	Quetiapine PR 200 mg (Test)	**Seroquel Prolong 200 mg (Reference)**	**Test/Ref Ratio (%)**		
$AUC_{0\text{-}tau}$ (ng h/mL)	3134.11	3118.90	100.49	96.36-104.80	
C_{max} (ng/mL)	278.41	267.54	104.06	97.26-111.34	22
C_{trough} (ng/mL)	41.54	43.82	94.80	84.09-106.86	

$AUC_{0\text{-}tau}$ area under the plasma concentration-time curve during a dosage interval at steady state
C_{max} maximum plasma concentration over a dosing interval
C_{trough} plasma concentration at the end of the dosing interval
CV coefficient of variation
Ratios and 90% CI calculated from log-transformed data

The 90% confidence intervals of the test/reference ratio for $AUC_{0\text{-}tau}$, C_{max} and C_{trough} lie within the acceptable limits. Thus, the data support the claim that the test product Quetiapine PR 200 mg Tablets (Teva Pharmaceutical Works Private Limited Company, Hungary) is bioequivalent to the reference product Seroquel Prolong 200 mg Retardtabletten (AstraZeneca GmbH, Germany) at steady state in healthy subjects after multiple doses, under fasting conditions.

Study 8
A randomised, open label, multiple-dose, four-period, two-sequence, two-treatment, replicate, crossover study comparing the pharmacokinetics of the test product A, Quetiapine PR 300 mg Tablets and the reference product B, Seroquel XR 300 mg Tablets (AstraZeneca BV, Netherlands), in male and female subjects with primary psychotic and/or bipolar disorder under fasting conditions.

<u>At admission on Day −3</u>
The subjects followed the tapering schedule provided by the investigator.

<u>Pre-dose Washout (Days −2 and −1)</u>
Subjects were restricted from taking quetiapine for at least 48 hours prior to drug administration on Day 0.

<u>Titration (Additional Product, Day 0)</u>
On Day 0, following the pre-study washout and prior to the administration of the study drug, subjects received a single, oral dose of Seroquel XR 200 mg Tablets (AstraZeneca Canada Inc., Canada) with

240 mL of room temperature potable water after an overnight fast of at least 10 hours. The use of a non-EU product is acceptable in this context (initial dose titration) as, based on the elimination half-life of about 7 hours it would be making a negligible contribution to the blood levels .by Day 5 of the study (first sampling day).

Dosing and Blood sampling (Days 1-17)

The subjects were given 300 mg of either treatment with 240ml of water after an overnight fast. The study drugs were administered once daily for 17 days over four treatment periods. The subjects were randomly assigned to one of the two dosing sequences ABAB or BABA. Blood samples were collected before each administration on Days 0, 3, 4, 7, 8, 11, 12, 15, and 16, and before and up to 24 hours after each administration on Days 5, 9 and 13 and 17. There was no washout period between the treatment periods. The pharmacokinetic results are presented below:

Pharmacokinetic parameters (arithmetic means) of quetiapine

Parameters (Units)	First Administration		Second Administration	
	Quetiapine PR 300 mg (Test)	**Seroquel XR 300 mg (Reference)**	**Quetiapine PR 300 mg (Test)**	**Seroquel XR 300 mg (Reference)**
$AUC_{0\text{-}tau}$ (ng.mL/h)	4039.96	4039.24	3731.46	3774.66
C_{max} (ng/mL)	407.45	382.55	375.00	399.03
C_{trough} (ng/mL)	49.21	55.43	48.36	53.01

$AUC_{0\text{-}tau}$ area under the plasma concentration-time curve during a dosage interval at steady state
C_{max} maximum plasma concentration
C_{trough} plasma concentration at the end of the dosing interval

Pharmacokinetic parameters (geometric means, ratios and confidence intervals [CI]) of quetiapine)

Parameters(Units)	**Ln-transformed Geometric Means and its Ratio**			**90% Confidence Interval (ln-transformed)**	**CV (%)**
	Quetiapine PR 300 mg (Test)	**Seroquel XR 300 mg (Reference)**	**Test/Ref Ratio (%)**		
$AUC_{0\text{-}t}$ (ng h/mL)	3507.39	3498.34	100.26	97.50-103.10	
C_{max} (ng/mL)	346.38	342.57	101.11	94.73-107.93	23
C_{trough} (ng/mL)	37.70	43.19	87.30	81.05-94.02	

$AUC_{0\text{-}tau}$ area under the plasma concentration-time curve during a dosage interval at steady state
C_{max} maximum plasma concentration over a dosing interval
C_{trough} plasma concentration at the end of the dosing interval
CV coefficient of variation
Ratios and 90% CI calculated from log-transformed data

The 90% confidence intervals of the test/reference ratio for $AUC_{0\text{-}tau}$, C_{max} and C_{trough} lie within the acceptable limits. Thus, the data support the claim that the test product Quetipine PR 300 mg Tablets is bioequivalent to the reference product Seroquel XR 300 mg Tablets (AstraZeneca BV, Netherlands) at steady-state in subjects with primary psychotic and/or bipolar disorder, after multiple doses, under fasting conditions.

Overall Conclusion on Bioequivalence
Based on the submitted bioequivalence studies, Quetiapine PR 50 mg, 200 mg, 300 mg and 400 mg Tablets are considered bioequivalent with the corresponding strength reference products used in the bioequivalence studies.

As the Dutch and German reference products used in the bioequivalence studies are considered identical to the corresponding strength reference products in the UK, bioequivalence has also been shown between the Sondate XL 50 mg, 200 mg, 300 mg and 400 mg Tablets and their respective UK reference products (Seroquel XL 50 mg, 200 mg, 300 mg and 400 mg prolonged-release tablets).

IV.3 Pharmacodynamics
No new pharmacodynamic data were submitted and none were required for these applications.

IV.4 Clinical Efficacy
The efficacy of quetiapine fumarate is well-known. No new efficacy data have been submitted and none are required for applications of this type.

IV.5 Clinical Safety
With the exception of the safety data generated during the bioequivalence studies, no new safety data were submitted and none are required for applications of this type. No new or unexpected safety issues arose during the bioequivalence studies.

IV.6 Risk Management Plan
The Pharmacovigilance System, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

A Risk Management Plan has been set for the reference product Seroquel XR, with some provisions that also need to be applied for generic products. A formal Risk Management Plan is not considered necessary however the Marketing Authorisation has provided a post-approval commitment to comply with special measures now requested for quetiapine.

IV.7 Discussion of the clinical aspects
It is recommended that Marketing Authorisations are granted from a clinical point of view.

V USER CONSULTATION
A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC, as amended. The leaflet conforms to the requirements. The test shows that the patients/users are able to act upon the information that the leaflet contains.

VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION
The quality characteristics of Sondate/Quelento/Sarparm XL 50, 200, 300 and 400 mg Prolonged-release Tablets (PL 00289/1219-22 and PL 00289/1506-13; UK/H/2074 and UK/H/4674-5/01-4/DC) are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

No new non-clinical data were submitted. As the pharmacokinetics, pharmacodynamics and toxicology of quetiapine fumarate are well-known, no additional data were required.

With the exception of the bioequivalence studies, no new data were submitted and none are required for applications of this type.

Bioequivalence has been demonstrated between the applicant's Sondate XL 50 mg, 200 mg, 300 mg and 400 mg prolonged-release tablets and their respective reference products Seroquel XL 50 mg, 200 mg, 300 mg and 400 mg prolonged-release tablets (AstraZeneca UK Limited, UK).

With the exception of the safety data from the bioequivalence studies, no new data were submitted and none are required for applications of this type. As the safety profile of quetiapine fumarate is well known, no additional data were required. No new or unexpected safety concerns arose from the bioequivalence studies.

The SmPCs, PILs and labelling are satisfactory, and consistent with those for the reference products, where appropriate, along with current guidelines.

BENEFIT/RISK ASSESSMENT

The quality of the products is acceptable, and no non-clinical or clinical concerns have been identified. Extensive clinical experience with quetiapine fumarate is considered to have demonstrated the therapeutic value of the products. The products are considered bioequivalent to the corresponding reference products and their benefit/risk balance is, therefore, also considered to be positive.

Summary of Product Characteristics, Patient Information Leaflet & Labels

In accordance with Directive 2012/84/EU, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website. The current approved UK labelling is presented in annex 1.

Please note the below variation only relates to PL 00289/1506-13.

Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

The following table lists non-safety update to the Marketing Authorisations for these products that has been approved by the MHRA since the products were first licensed. The table includes updates that are detailed in the annex to this PAR. This is not a complete list of the post-authorisation changes that have been made to these Marketing Authorisations.

Scope	Procedure numbers	Product information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached Y/N (version)
To update sections 3 & 6.5 of the SmPC and labelling in line with recommended wording agreed by competent authorities that may require additional minor assessment following a repeat use procedure. Additionally, the SmPC has been aligned with the Quality review of documents (QRD) template.	UK/H/4674/001, 3-5/II/024 UK/H/4675/001-4/II/024	SmPC and labelling	17/05/2017	04/08/2017	Approval	Yes
Update the SmPC, PIL, and Labelling in line with recommended wording agreed by competent authorities that may require additional minor assessment following a repeat use procedure. The proposed wording was proposed by concerned member states Sweden and France during repeat use procedure UK/H/2074/001-005/E/002 in line with the current QRD template (Rev 9 February 2016.)	UK/H/2074/001-4/II/027	SmPC, PIL and Labelling	17/05/2017	08/12/2017	Approval	Yes

Please note the below variation only relates to PL 00289/1506-13.

Annex 1

Reference: **PL 00289/1506 – 0039, PL 00289/1507 – 0039, PL 00289/1508 – 0038 and PL 00289/1509 – 0038, PL 00289/1510 – 0041, PL 00289/1511 – 0040, PL 00289/1512 – 0040, PL 00289/1513 - 0040**

Product: **Quelento/Sarparm XL 50, 200, 300 and 400 mg Prolonged-release Tablets**

Marketing Authorisation Holder: TEVA UK Limited

Active Ingredient: **Quetiapine fumarate**

Reason:

To update sections 3 & 6.5 of the SmPC and labelling in line with recommended wording agreed by competent authorities that may require additional minor assessment following a repeat use procedure. Additionally, the SmPC has been aligned with the QRD template.

Supporting evidence

The applicant has submitted updated sections of the SmPC, PIL and label.

Evaluation

The amended sections of the SmPC, PIL and labelling are satisfactory. These proposed changes appear acceptable.

Conclusion

The updated SmPC fragments and the labelling have been incorporated into these Marketing Authorisations. The proposed changes are acceptable.

Decision: Grant

Date: 04 August 2017

The current approved UK labelling Quelento/Sarparm XL 50, 200, 300 and 400 mg is presented below:

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of bottles

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 50 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 50 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1506

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor.

16. INFORMATION IN BRAILLE

Quelento XL 50 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 50 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 50 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S) IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1506

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS FOR USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 50 mg prolonged-release tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

In case no outer packaging is used
<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

In case no outer packaging is used
<PC:
SN:
NN:>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of blisters

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 50 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 50 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

10 prolonged-release tablets
20 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablet
50x1prolonged-release tablet
56 prolonged-release tablets calendar pack
60 prolonged-release tablets
90 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

FLASH
New advice for drivers – see leaflet inside

BACK OF PACK

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1506

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 50 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 50 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER – CALENDAR PACK

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 50 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of bottles

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 200 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 200 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

10 prolonged-release tablets
20 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablet
50x1prolonged-release tablet
56 prolonged-release tablets calendar pack
60 prolonged-release tablets
90 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Limited, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1507

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 200 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Quelento XL 200 mg Prolonged-releaseTtablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 200 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

EXP

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S) IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Limited, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1507

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS FOR USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 200 mg prolonged-release tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

In case no outer packaging is used
<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

In case no outer packaging is used
<PC:
SN:
NN:>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of blisters

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 200 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 200 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

10 prolonged-release tablets
20 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablet
50x1prolonged-release tablet
56 prolonged-release tablets calendar pack
60 prolonged-release tablets
90 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not slpit, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

FLASH
New advice for drivers – see leaflet inside

BACK OF PACK

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Limited, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1507

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 200 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 200 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER – CALENDAR PACK

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 200 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of bottles

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 300 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 300 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1508

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed on the doctor

16. INFORMATION IN BRAILLE

Quelento XL 300 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Quelento XL 300 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 300 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S) IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1508

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS FOR USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 300 mg prolonged-release tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

In case no outer packaging is used
<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

In case no outer packaging is used
<PC:
SN:
NN:>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of blisters

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 300 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 300 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

10 prolonged-release tablets
20 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablet
50x1prolonged-release tablet
56 prolonged-release tablets calendar pack
60 prolonged-release tablets
90 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

FLASH
New advice for drivers – see leaflet inside

BACK OF PACK

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1508

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 300 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 300 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER – CALENDAR PACK

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 300 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of bottles

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 400 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 400 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1509

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 400 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 400 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 400 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S) IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1509

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS FOR USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 400 mg prolonged-release tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

In case no outer packaging is used
<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

In case no outer packaging is used
<PC:
SN:
NN:>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of blisters

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 400 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 400 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

10 prolonged-release tablets
20 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablet
50x1prolonged-release tablet
56 prolonged-release tablets calendar pack
60 prolonged-release tablets
90 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

FLASH
New advice for drivers – see leaflet inside

BACK OF PACK

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1509

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

Quelento XL 400 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 400 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER – CALENDAR PACK

1. NAME OF THE MEDICINAL PRODUCT

Quelento XL 400 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of bottles

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 50 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 50 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1510

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor.

16. INFORMATION IN BRAILLE

SARPARM XL 50 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 50 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 50 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S) IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1510

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS FOR USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 50 mg prolonged-release tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

In case no outer packaging is used
<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

In case no outer packaging is used
<PC:
SN:
NN:>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of blisters

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 50 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 50 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

10 prolonged-release tablets
20 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablet
50x1prolonged-release tablet
56 prolonged-release tablets calendar pack
60 prolonged-release tablets
90 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

FLASH
New advice for drivers – see leaflet inside

BACK OF PACK

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1510

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 50 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 50 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER – CALENDAR PACK

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 50 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of bottles

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 200 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 200 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1511

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 200 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

SARPARM XL 200 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 200 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

EXP

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S) IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1511

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS FOR USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 200 mg prolonged-release tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

In case no outer packaging is used
<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

In case no outer packaging is used
<PC:
SN:
NN:>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of blisters

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 200 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 200 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

10 prolonged-release tablets
20 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablet
50x1prolonged-release tablet
56 prolonged-release tablets calendar pack
60 prolonged-release tablets
90 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not slpit, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

FLASH
New advice for drivers – see leaflet inside

BACK OF PACK

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1511

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 200 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 200 mg Prolonged-release Tablets
Quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER – CALENDAR PACK

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 200 mg Prolonged-release Tablets

quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of bottles

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 300 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 300 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1512

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed on the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 300 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

SARPARM XL 300 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 300 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S) IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1512

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS FOR USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 300 mg prolonged-release tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

In case no outer packaging is used
<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

In case no outer packaging is used
<PC:
SN:
NN:>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of blisters

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 300 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 300 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

10 prolonged-release tablets
20 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablet
50x1prolonged-release tablet
56 prolonged-release tablets calendar pack
60 prolonged-release tablets
90 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

FLASH
New advice for drivers – see leaflet inside

BACK OF PACK

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TeEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1512

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 300 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 300 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER – CALENDAR PACK

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 300 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of bottles

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 400 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 400 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1513

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 400 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 400 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 400 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

60 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S) IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1513

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS FOR USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 400 mg prolonged-release tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

In case no outer packaging is used
<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

In case no outer packaging is used
<PC:
SN:
NN:>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON of blisters

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 400 mg Prolonged-release Tablets
quetiapine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each prolonged-release tablet contains 400 mg quetiapine (as fumarate)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Prolonged-release Tablet

10 prolonged-release tablets
20 prolonged-release tablets
30 prolonged-release tablets
50 prolonged-release tablet
50x1prolonged-release tablet
56 prolonged-release tablets calendar pack
60 prolonged-release tablets
90 prolonged-release tablets
100 prolonged-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not split, chew or crush the tablets.
Oral use
Please read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

FLASH
New advice for drivers – see leaflet inside

BACK OF PACK

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TEVA UK Ltd, Eastbourne, BN22 9AG

12. MARKETING AUTHORISATION NUMBER(S)

PL 00289/1513

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by the doctor

16. INFORMATION IN BRAILLE

SARPARM XL 400 mg prolonged-release tablets

17. UNIQUE IDENTIFIER - 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 400 mg Prolonged-release Tablets
quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER – CALENDAR PACK

1. NAME OF THE MEDICINAL PRODUCT

SARPARM XL 400 mg Prolonged-release Tablets

quetiapine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: TEVA UK Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday

Please note the below variation only relates to PL 00289/1219-1222.

Annex 2

Reference: **PL 00289/1219 – 0046, PL 00289/1220 – 0046, PL 00289/1221 – 0046 and PL 00289/1222 – 0046**
Product: **Sondate XL 50, 200, 300 and 400 mg Prolonged-release Tablets**

Marketing Authorisation Holder: TEVA UK Limited

Active Ingredient: **Quetiapine fumarate**
Reason:
To update the SmPC, PIL, and Labelling in line with recommended wording agreed by competent authorities that may require additional minor assessment following a repeat use procedure. The proposed wording was proposed by the concerned (CMS) Sweden and France during repeat use procedure UK/H/2074/001-004/E/002 in line with the current Quality Review of Documents (QRD) template (Rev 9 February 2016).

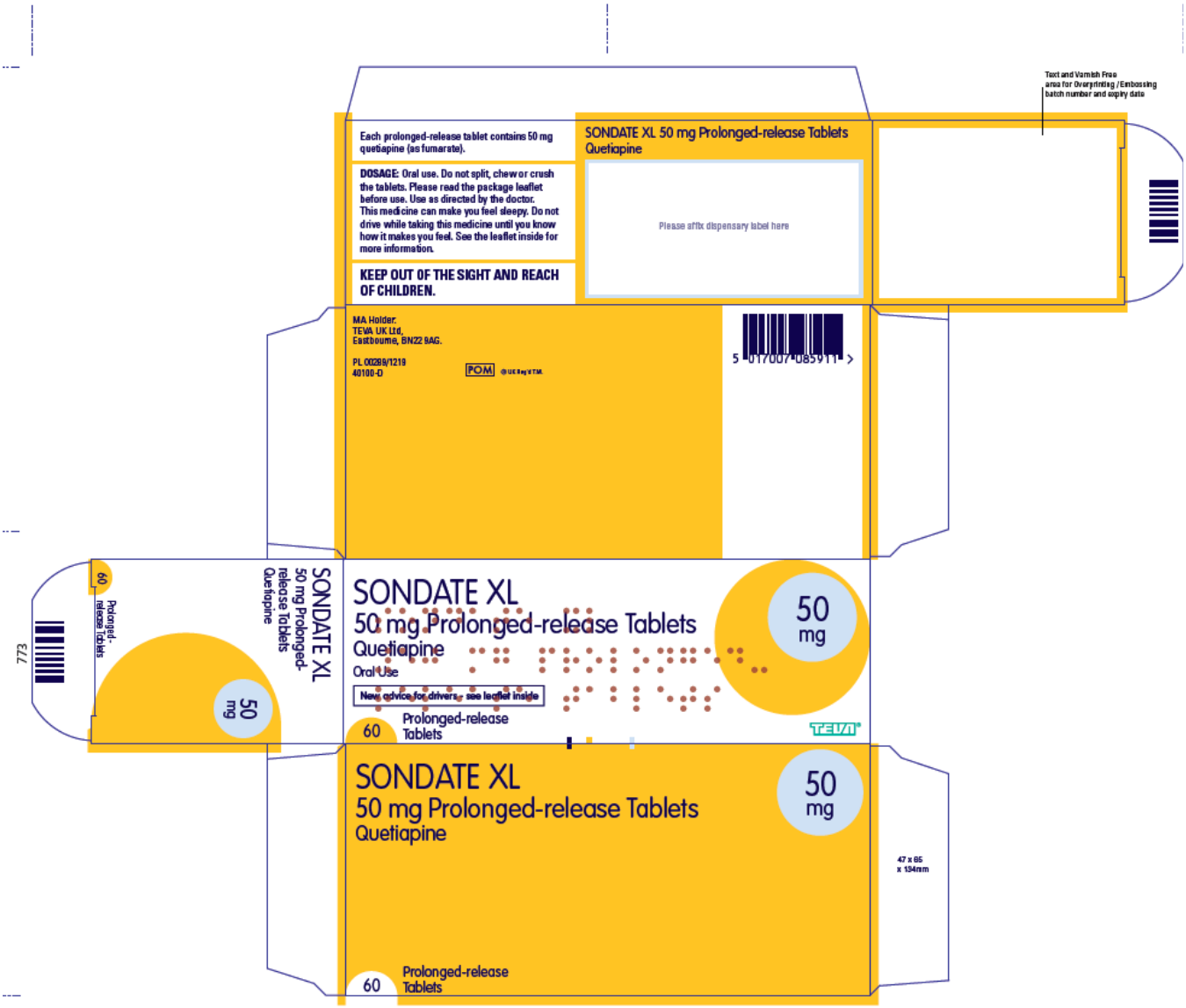
Supporting evidence
The applicant has submitted updated sections of the SmPC, PIL and label.

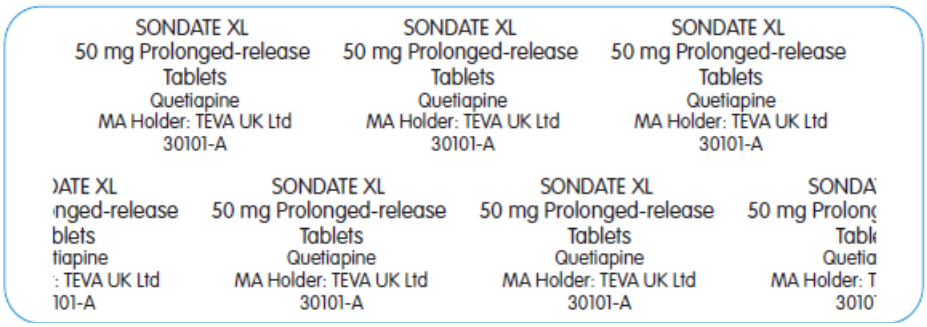
Evaluation
The amended sections of the SmPC, PIL and labelling are satisfactory. These proposed changes appear acceptable.

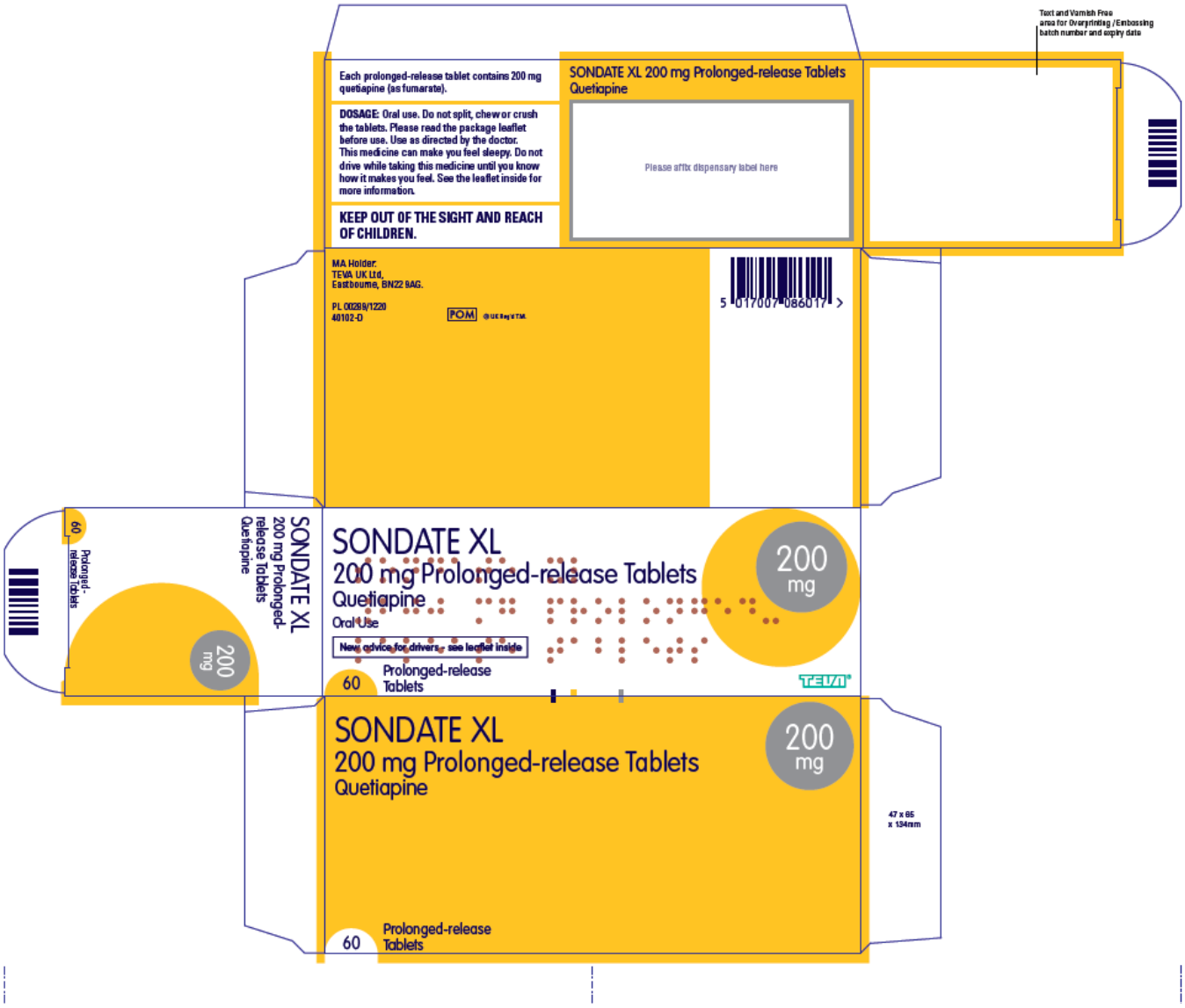
Conclusion
The updated SmPC fragments and the labelling have been incorporated into these Marketing Authorisations. The proposed changes are acceptable.

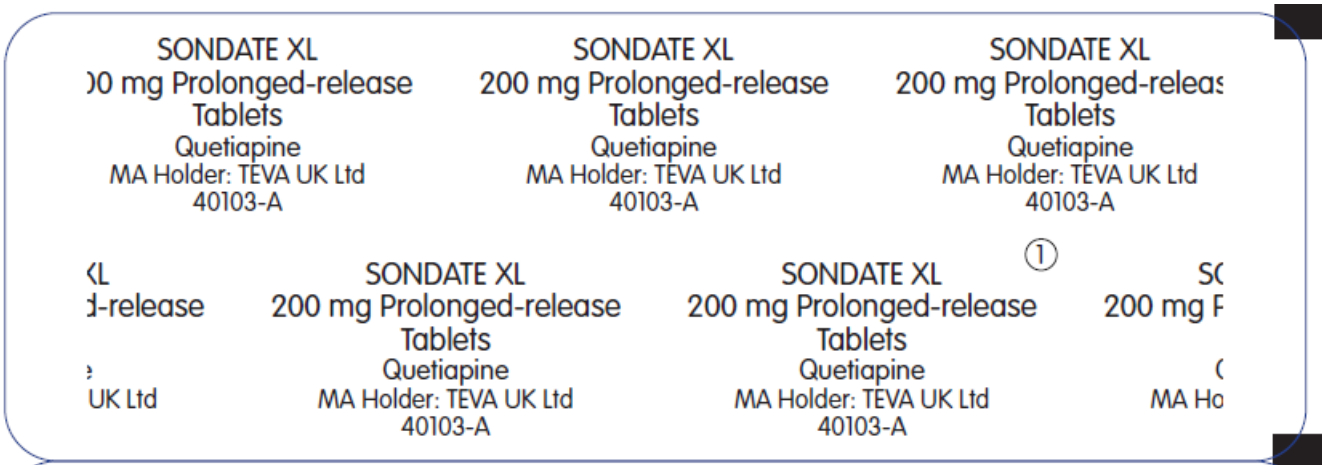
Decision: Grant
Date: 08 December 2017

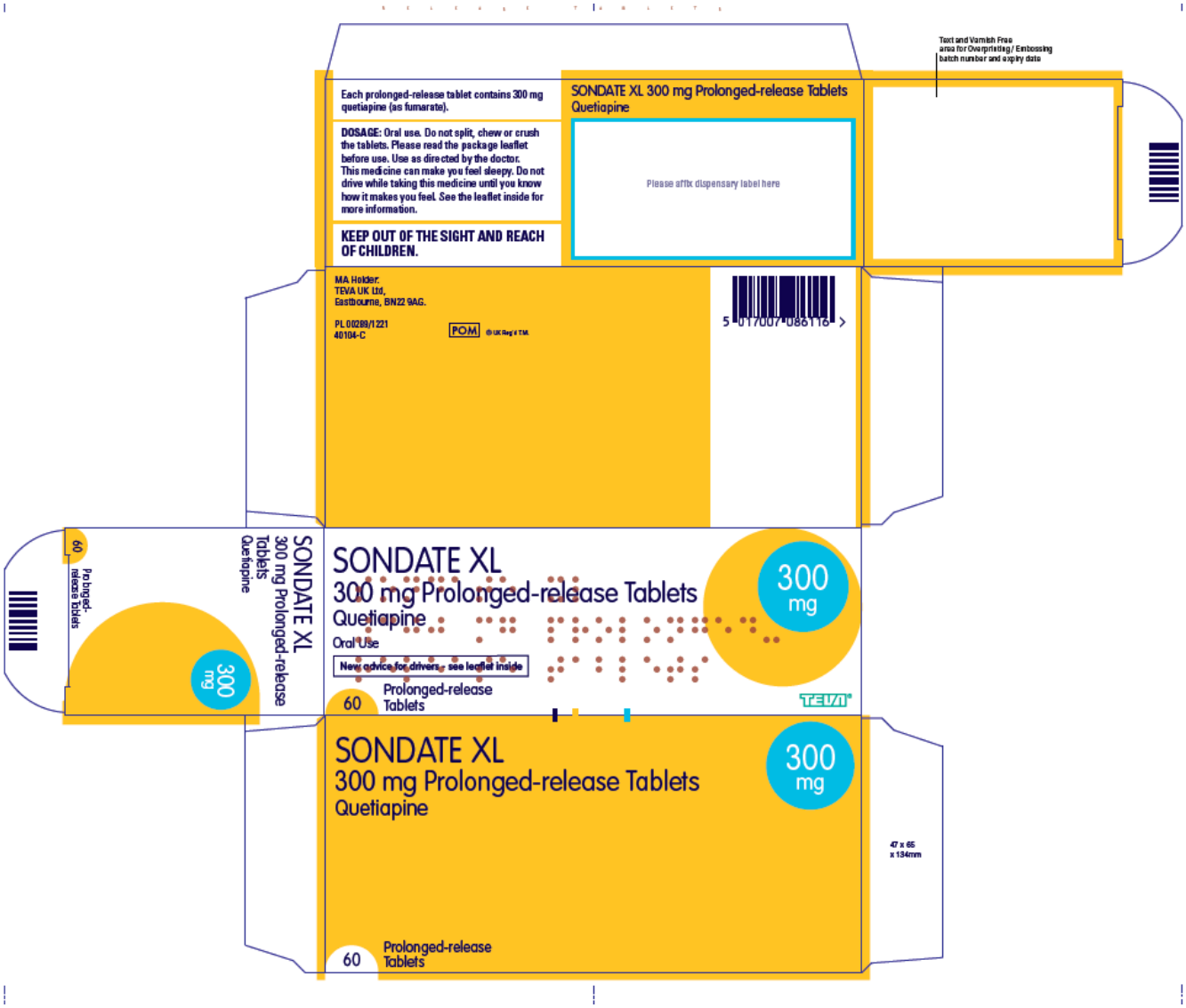
The current approved UK labelling for Sondate XL 50, 200, 300 and 400 mg is presented below:

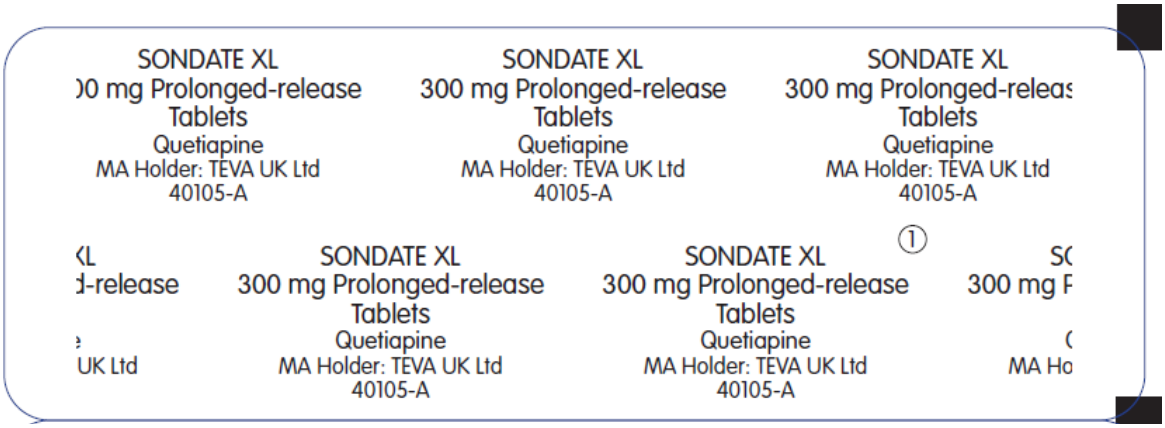


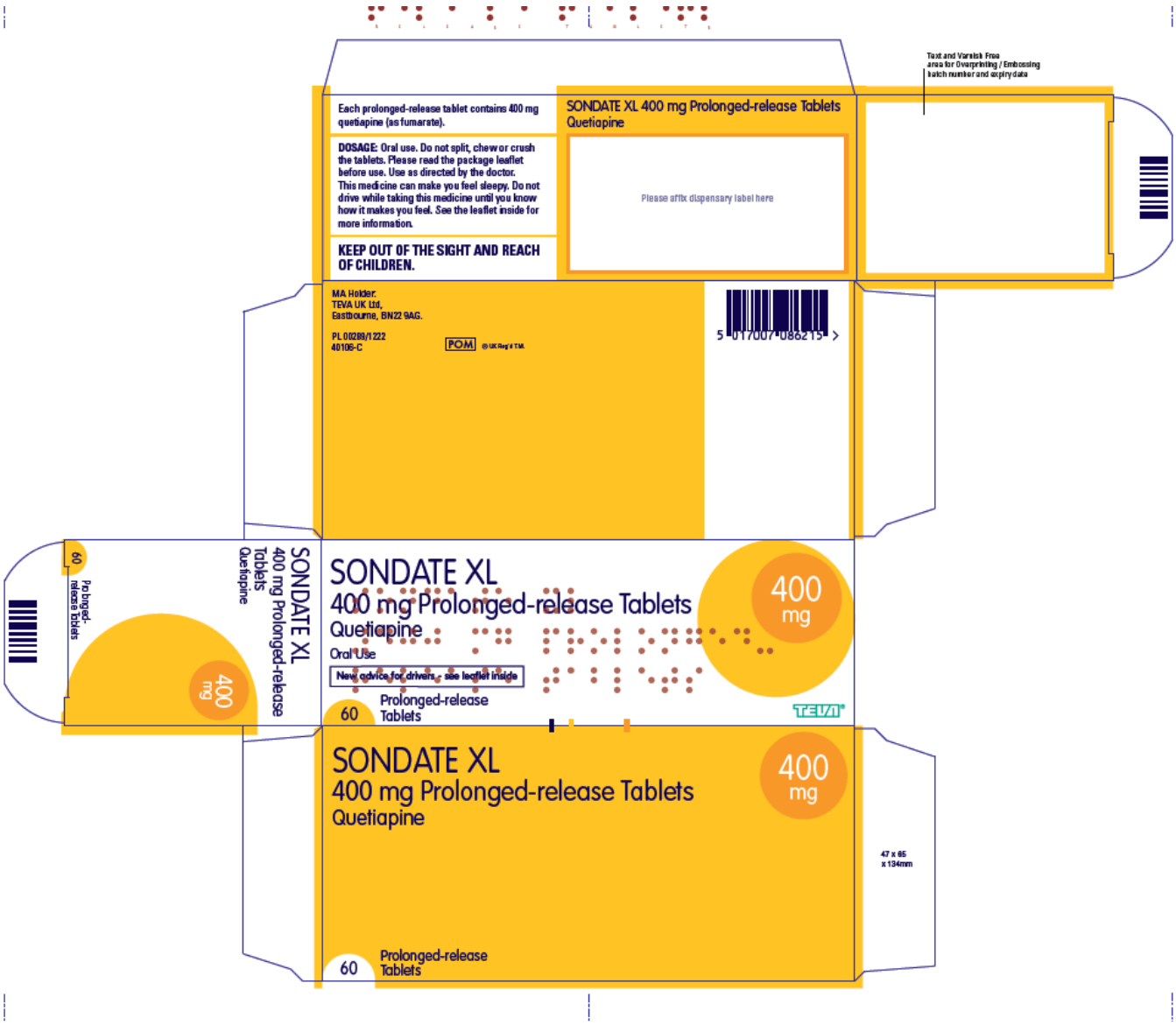


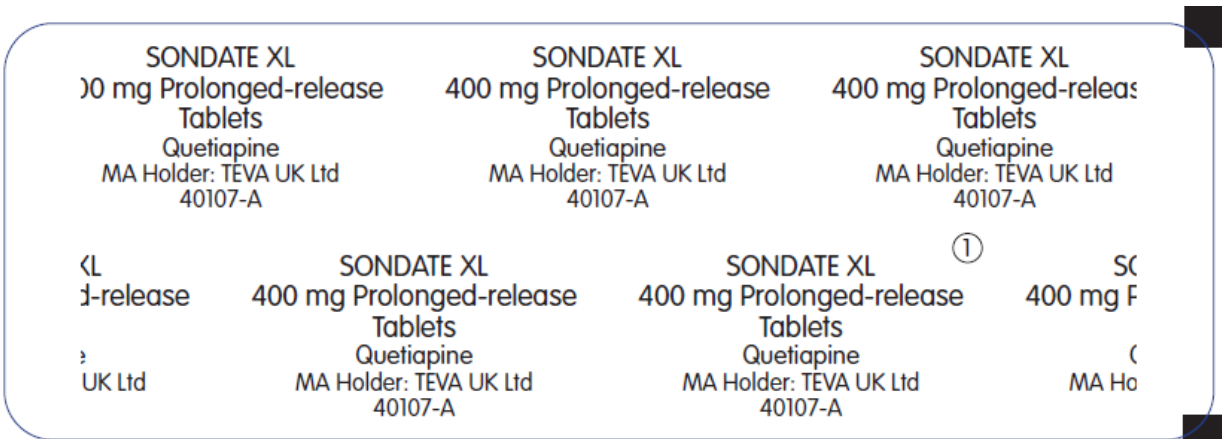

Text and Varnish Free area for Overprinting / Embossing batch number and expiry date
Each prolonged-release tablet contains 200 mg quetiapine (as fumarate).
DOSAGE: Oral use. Do not split, chew or crush the tablets. Please read the package leaflet before use. Use as directed by the doctor. This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
SONDATE XL 200 mg Prolonged-release Tablets
Quetiapine
Please affix dispensary label here
MA Holder:
TEVA UK Ltd,
Eastbourne, BN22 9AG.
PL 00289/1220
40102-0
POM
5 017007 086017
SONDATE XL
200 mg Prolonged-release Tablets
Quetiapine
Oral Use
New advice for drivers – see leaflet inside
60
Prolonged-release Tablets
200 mg
TEVA
SONDATE XL
200 mg Prolonged-release Tablets
Quetiapine
200 mg
60
Prolonged-release Tablets
47 x 85 x 134mm


SONDATE XL
)0 mg Prolonged-release Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40103-A
SONDATE XL
200 mg Prolonged-release Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40103-A
SONDATE XL
200 mg Prolonged-releas Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40103-A
①
KL
d-release
UK Ltd
SONDATE XL
200 mg Prolonged-release Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40103-A
SONDATE XL
200 mg Prolonged-release Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40103-A
SC
200 mg F
MA Ho


Text and Varnish Free area for Overprinting / Embossing batch number and expiry date
Each prolonged-release tablet contains 300 mg quetiapine (as fumarate).
DOSAGE: Oral use. Do not split, chew or crush the tablets. Please read the package leaflet before use. Use as directed by the doctor. This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
SONDATE XL 300 mg Prolonged-release Tablets
Quetiapine
Please affix dispensary label here
MA Holder:
TEVA UK Ltd,
Eastbourne, BN22 9AG.
PL 00289/1221
40104-C
POM
5 017007 086116
SONDATE XL
300 mg Prolonged-release Tablets
Quetiapine
Oral Use
New advice for drivers – see leaflet inside
60 Prolonged-release Tablets
300 mg
TEVA
SONDATE XL
300 mg Prolonged-release Tablets
Quetiapine
60
Prolonged-release Tablets
300 mg
47 x 65 x 134mm


SONDATE XL
300 mg Prolonged-release Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40105-A
SONDATE XL
300 mg Prolonged-release Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40105-A
SONDATE XL
300 mg Prolonged-release Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40105-A
SONDATE XL
300 mg Prolonged-release Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40105-A
SONDATE XL
300 mg Prolonged-release Tablets
Quetiapine
MA Holder: TEVA UK Ltd
40105-A


Text and Varnish Free area for Overprinting / Embossing batch number and expiry date
Each prolonged-release tablet contains 400 mg quetiapine (as fumarate).
DOSAGE: Oral use. Do not split, chew or crush the tablets. Please read the package leaflet before use. Use as directed by the doctor. This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
SONDATE XL 400 mg Prolonged-release Tablets Quetiapine
Please affix dispensary label here
MA Holder:
TEVA UK Ltd,
Eastbourne, BN22 9AG.
PL 00289/1222
40106-C
POM
5 017007 086215
SONDATE XL
400 mg Prolonged-release Tablets
Quetiapine
Oral Use
New advice for drivers - see leaflet inside
60
Prolonged-release Tablets
400 mg
TEVA
47 x 65 x 134mm


SONDATE XL
Quetiapine
MA Holder: TEVA UK Ltd
40107-A
①