

[Disclaimer: This template displays the important safety messages included in the medication guides for each ER/LA opioid analgesic drug. Please note, due to variability among the individual ER/LA opioid analgesic products, some sections below may be modified to convey product-specific safety information. For a complete list of all product-specific, FDA approved medication guides, including those for the ER/LA opioid analgesics, please visit <http://wcms.fda.gov/FDAgov/Drugs/DrugSafety/ucm085729.htm>]

Medication Guide

TRADENAME[®] *[Insert phonetic spelling]*
(chemical name) *[Insert dosage form]*, CII

TRADENAME is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not for use to treat pain that is not around-the-clock.

Important information about TRADENAME:

- **Get emergency help right away if you take too much TRADENAME (overdose).** When you first start taking TRADENAME, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Never give anyone else your TRADENAME. They could die from taking it. Store TRADENAME away from children and in a safe place to prevent stealing or abuse. Selling or giving away TRADENAME is against the law.

Do not take TRADENAME if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking TRADENAME, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of TRADENAME during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** TRADENAME passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking TRADENAME with certain other medicines can cause serious side effects that could lead to death.

When taking TRADENAME:

- Do not change your dose. Take TRADENAME exactly as prescribed by your healthcare provider.
- Take your prescribed dose *[insert frequency, e.g., every X hours at the same time every day]*. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Swallow TRADENAME whole. Do not cut, break, chew, crush, dissolve, snort, or inject TRADENAME because this may cause you to overdose and die.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking TRADENAME without talking to your healthcare provider.**
- After you stop taking TRADENAME, flush any unused *[insert dosage form]* down the toilet.

While taking TRADENAME DO NOT:

- Drive or operate heavy machinery, until you know how TRADENAME affects you. TRADENAME can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with TRADENAME may cause you to overdose and die.

The possible side effects of TRADENAME:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, light-headedness when changing positions, or you are feeling faint.

These are not all the possible side effects of TRADENAME. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured by: *[Insert name and address]* and/or Distributed by: *[Insert name and address]*, www.TRADENAME.com or call 1-800-XXX-XXXX

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: month/year