



Introduction

Read the Patient Instructions for Use that comes with NovoPen 4 before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

NovoPen 4 is an insulin pen that can deliver insulin doses from 1 to 60 units, in increments of 1 unit. NovoPen 4 is designed to be used with PenFill 3 mL insulin cartridges and NovoFine disposable needles.

NovoFine disposable needles are for one time use only.

You should read the instructions in this manual even if you have used NovoPen 4 or other Novo Nordisk delivery systems before.

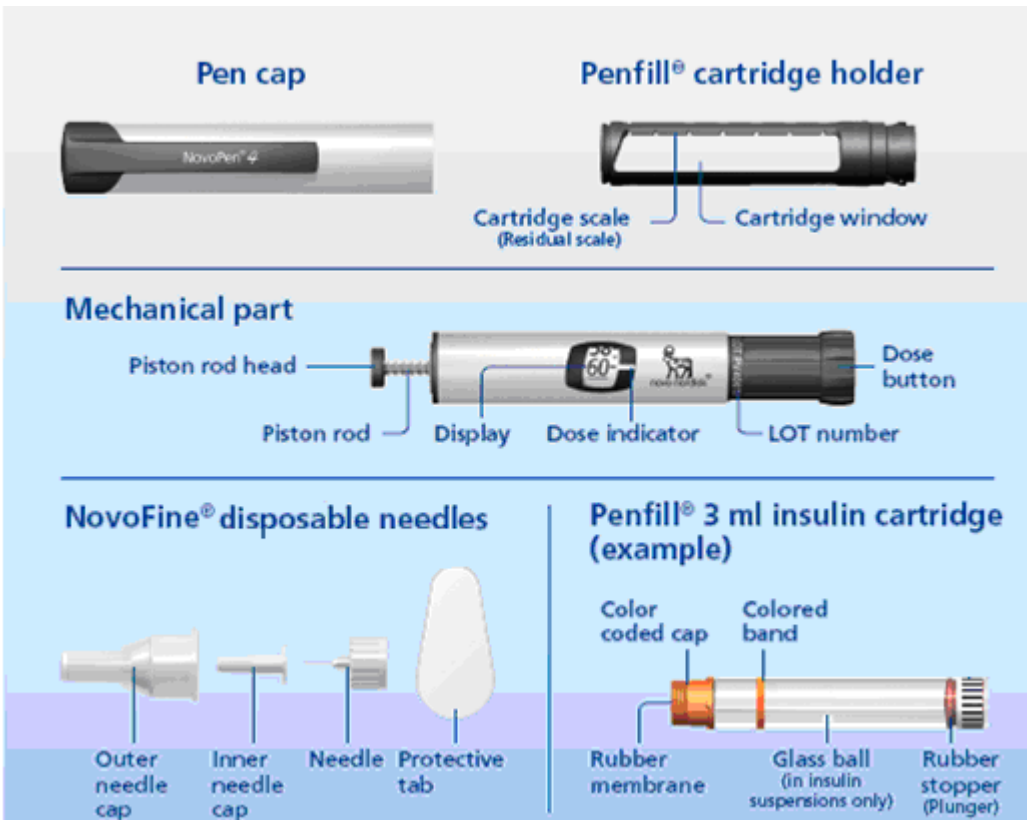
NovoPen 4 should not be used by people who are blind or have visual problems without the help of a person who has good eyesight and who is trained to use the NovoPen 4 the right way.

Getting Ready

Make sure you have the following items:

- NovoPen 4
- alcohol swabs
- PenFill 3 mL insulin cartridge
- NovoFine disposable needle





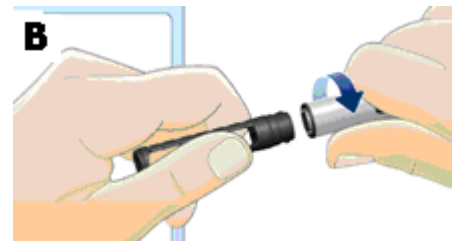
Preparing your NovoPen 4

Before you start to prepare your injection, check the label to make sure that you are taking the right type of insulin (such as Novolin R, Novolin N, Novolin 70/30, or NovoLog).

A. Pull off the cap. See Figure A.



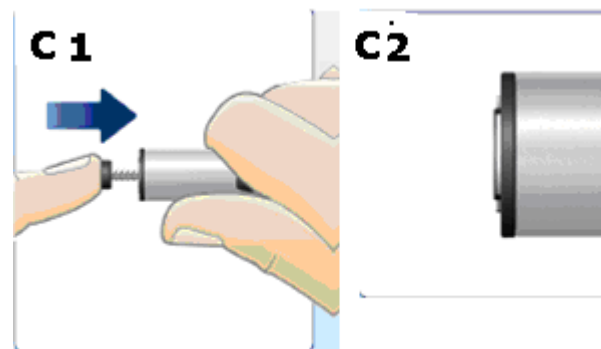
B. Unscrew and remove the cartridge holder from the mechanical part. See Figure B.



C. Push in the piston rod, by gently pressing the piston rod head (see Figure C1) in until it stops and looks like Figure C2.

Please note when NovoPen 4 is apart while removing the PenFill cartridge, the piston rod can move back and forth without pressing it.

If you use more than one kind of insulin, you should use a separate delivery device for each product.



D. Use a new PenFill cartridge.

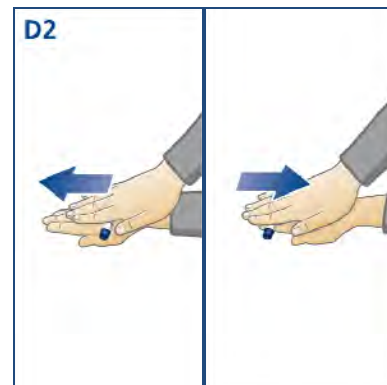
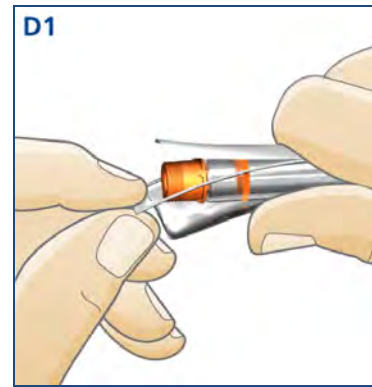
To remove the PenFill cartridge from its wrapper, push the cartridge through the foil side of the packaging (see Figure D1).

Before use, check that the PenFill cartridge is full and intact and with no cracks. If not, do not use it.

How to prepare (resuspend) the insulin if the PenFill cartridge contains an insulin suspension (white and cloudy insulin) such as Novolin 70/30 or Novolin N you must:

Before inserting a 3 mL cartridge into your NovoPen 4 for the first time:

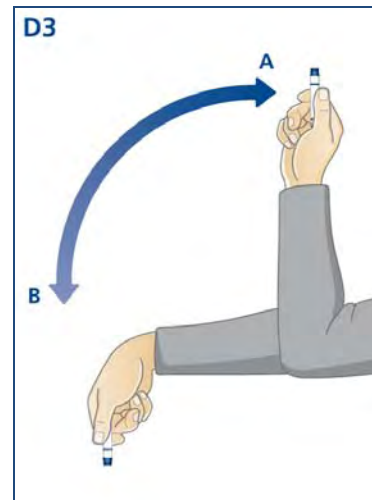
- Roll the PenFill cartridge between your hands 10 times. These steps should be done with the 3 mL PenFill cartridge in a flat (horizontal) position (see Figure D2)



- Then turn the PenFill cartridge up and down between positions **A** and **B** (see Figure D3) so the glass ball moves from one end of the cartridge to the other. Do this at least 10 times. Repeat the rolling and turning steps until the insulin looks white and cloudy. Mixing is easier when the insulin is at room temperature.

After the first use of the 3 mL PenFill cartridge

- With the cartridge in the NovoPen 4, turn it upside down between positions **A** and **B** (see Figure D3 above), so that the glass ball moves from one end of the 3 mL PenFill cartridge to the other. Do this until all of the insulin looks white and cloudy.
- Before you inject your insulin:
 - make sure there is at least 12 units of insulin left in the cartridge this helps to make sure that the remaining insulin is evenly mixed. If there is less than 12 units left in the cartridge, use a new 3 mL PenFill cartridge.

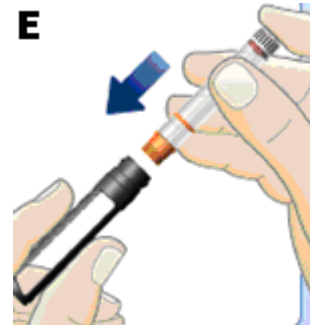


Each PenFill 3 mL cartridge contains a total of 300 units of insulin. There are five cartridges in a box. Each PenFill cartridge is for only one person to use.

DO NOT share your NovoPen 4 with other people even if they have diabetes. Sharing the PenFill cartridge can spread disease.

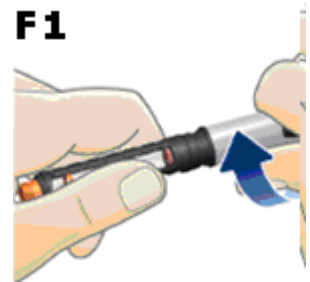
Use only a new PenFill 3 mL cartridge when loading the NovoPen 4. Never load a partially filled PenFill cartridge. Never try to refill a used PenFill 3 mL cartridge.

E. Insert the PenFill cartridge into the cartridge holder, colored cap first. See Figure E.



You can see the PenFill cartridge scale in the cartridge window. The cartridge holder has a scale with marks showing about how much insulin is left in the PenFill cartridge.

F. Screw the mechanical part together with the cartridge holder until you hear or feel a click. See Figure F1.

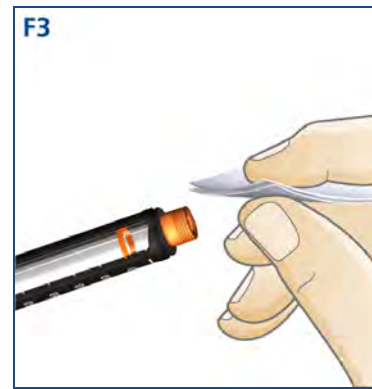


Before each injection, check the amount of insulin left in the PenFill cartridge:

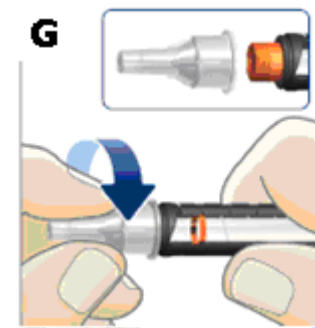
- If the rear rubber stopper cannot be seen in the cartridge window, you have enough insulin for mixing left in the PenFill cartridge. See Figure F2.
- If the rear rubber stopper can be seen in the cartridge holder window, you do not have enough insulin left in the PenFill cartridge and must use a new PenFill 3 mL cartridge.



Wipe the rubber stopper with an alcohol swab. See Figure F3.



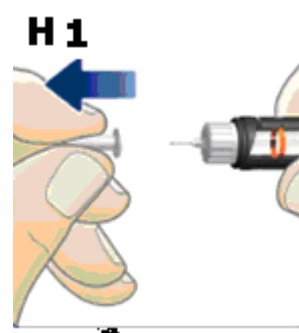
G. Remove the protective tab from a NovoFine disposable needle. Screw the needle tightly onto the colored cap. See Figure G.



Always use a new NovoFine disposable needle for each injection.

Never place a NovoFine disposable needle on your NovoPen 4 until you are ready to do an air shot and take your injection.

H. Pull off the outer needle cap. Carefully pull off the inner needle cap and throw it away. See Figure H1. A droplet of insulin may appear at the needle tip. This is normal.



Do not bend or damage the needle. To lessen the risk of unexpected needle sticks, never put the inner needle cap back on the needle.

Always take off the needle after each injection and store the NovoPen 4 without a needle attached. This prevents contamination, infection, leakage of insulin, and will ensure accurate dosing.

Do an “Air Shot” before each injection

Before each injection a small amount of air may collect in the PenFill cartridge. To avoid injecting air and ensure proper dosing, you must do an air shot before each injection.

Before starting the air shot, the dose indicator window must show zero (0) see Figure H2.



Set the NovoPen 4 for the air shot:

I. Make sure that a NovoFine disposable needle is attached. See Figure I.



J. Pull out the dose button, if it is not already pulled out. See Figure J.

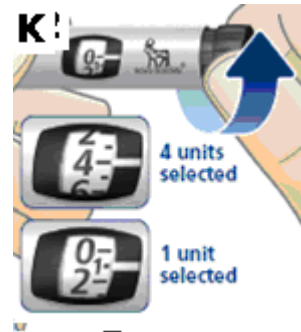


K. Turn the dose button to select:

- 4 units with a new PenFill cartridge. 4 units are selected when the number 4 lines up with the dose indicator. See Figure K.

OR

- 1 unit with a cartridge already in use. 1 unit is selected when the number 1 lines up with the dose indicator. See Figure K.



1 increment is equal to 1 unit.

The even numbers are shown. The odd numbers are indicated by the lines between the even numbers.

L. Hold your NovoPen 4 with the needle pointing up.

Tap the PenFill cartridge holder gently with your finger a few times to make any air bubbles collect at the top of the cartridge. See Figure L.



M. Keep the needle pointing up, press the dose button all the way in, until you hear or feel a click. The display will return to 0.

A drop of insulin must appear at the needle tip. See Figure M. If you do not see a drop of insulin at the needle tip, repeat steps I to L until you see a drop of insulin at the needle tip. You may need to do this up to 6 times. If you do not see a drop of insulin after 6 times, do not use the NovoPen 4 and call Novo Nordisk at 1-800-727-6500.

It is very important that a drop of insulin is seen at the needle tip before you take your injection. This will ensure accurate dosing. A small air bubble may remain in the PenFill cartridge. This is normal it will not affect your dose and will not be injected.

Select your dose

Be sure to do an air shot before giving an injection.

N. Pull out the dose button, if it is not already pulled out. See Figure N.

O. Turn the dose button to the number of units you need to inject. The pointer should line up with your dose that is needed. Remember that 60 units is the maximum dose you can take in one injection. See Figure O.

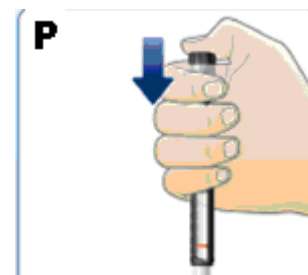
If you select a different dose than you need, turn the dose button until the correct dose lines up with the dose indicator.

If you need more than 60 units, you must divide your dose into two injections. Inject the 60 units first and then make a new injection with the remaining number of units needed to complete your dose. For example, to inject 65 units you must inject 60 units first and then make a new injection with 5 units of insulin to complete your dose. **Always use a new disposable needle for each injection.** See Figure O.

Give your injection

Give the injection exactly as shown to you by your healthcare provider.

P. Insert the needle into your skin. Inject the dose by pressing the dose button all the way in, until you hear or feel a click. Check the dose indicator window to make sure it shows zero (0). See Figure P.



Q. Keep the NovoFine needle in the skin for at least 6 seconds. See Figure Q

This will make sure that the full insulin dose has is given.



Be careful only to press the dose button to inject the insulin. Turning the dose button will not inject insulin.

R. Take the needle out of your skin. You have completed your injection and the selected insulin dose has been given. The display will show 0. If zero (0) does not appear, you did not get the full dose. See Figure R.

After you take the needle out of your skin, you may see a few drops of insulin at the needle tip. This is normal and has no effect on the dose you just received.



If your injection is given by another person, this person must be careful when removing and disposing of needles to prevent accidental needle stick injury.

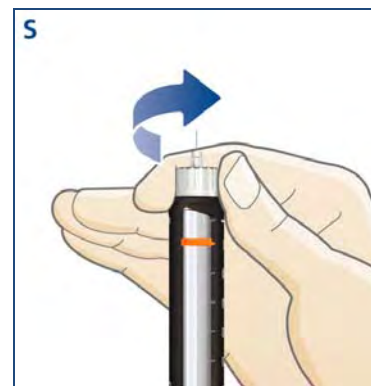
After the injection

The NovoFine disposable needle must be removed immediately after each injection without replacing the cap.

Do not recap the needle. Recapping can lead to a needle stick injury. Remove the needle from the NovoPen 4 after each injection. This helps to prevent infection, leakage of insulin, and will help to make sure you inject the right dose of insulin.

S. Carefully remove the needle (see Figure S), put the needle and any empty PenFill cartridge in a sharps container, or some type of hard plastic or metal container with a screw top such as a detergent bottle or empty coffee can. These containers should be sealed and thrown away the right way. Check with your healthcare provider about the right way to throw away used needles and syringes. There may be local or state laws about how to throw away used needles. Do not throw away used needles in household trash or recycling bins.

- Always replace the pen cap after each use.



Put the pen cap on the NovoPen 4 and store the NovoPen 4 without the needle attached. This helps to ensure sterility, prevent leakage of insulin, and will help to make sure you inject the right dose of insulin with your next injection.

Change the PenFill cartridge

When the PenFill cartridge is almost empty:

T. The cartridge scale on the PenFill cartridge holder shows the approximate number of insulin units left in the PenFill cartridge as in Figure A. Do not use the cartridge scale to measure the amount of insulin to be injected. See Figure T.

U. If the PenFill cartridge has less than 60 units in it, the exact number of units left can be read in the display. To do this, pull out the dose button, if it is not already pulled out, and turn it until it stops. The number of units left will line up with the dose indicator as seen in Figure B. If the dose indicator is positioned between two lines, adjust to the lower of the two dose amounts. You can not select a dose larger than the number of units left in the PenFill cartridge. See Figure U.

Do not force the dose button to turn as this can damage your NovoPen 4.

Insulin suspension (white and cloudy insulin):

V. Do not try to inject an insulin suspension (white and cloudy insulin) if the rubber stopper (plunger) is below the white line on the holder as in Figure V. The glass ball inside the PenFill cartridge must have enough space to mix the insulin.

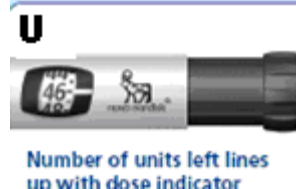
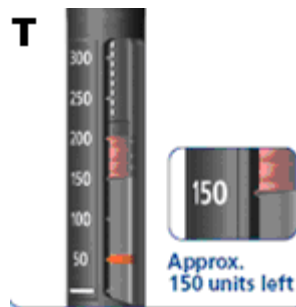
If you need more insulin than the amount left in the PenFill cartridge, you can:

- Inject the amount of insulin left in the PenFill cartridge, making a note of the number of units you inject or replace the used PenFill cartridge with a new one for your full dose.
- To change the PenFill cartridge see Figure T to U.
- Always attach a new NovoFine needle.
- Do an airshot as described in Figure I to M.
- Select and inject the number of insulin units needed to complete your dose.

Storage

Storage and handling

- Be careful when handling your NovoPen 4, do not drop it and avoid knocking it against hard surfaces.
- Always remove the needle and replace the pen cap after each use.



- Protect your NovoPen 4 against direct sunlight, water, dust and dirt.
- When a PenFill cartridge is inserted in the NovoPen 4, store your NovoPen 4 at 59°F to 86°F (15°C to 30°C) for the amount of days listed in the PenFill “Information for the Patient” leaflet for the type of insulin you are using.
- The expiration date printed on the PenFill cartridge is for unused PenFill cartridges stored in the refrigerator. Never use the PenFill cartridge after the expiration date on the PenFill cartridge or on the box.
- For information on storing PenFill cartridges, see the Information For The Patient leaflet that comes in the PenFill cartridge box.
- Keep your NovoPen 4 in the case supplied when possible.

Maintenance

Cleaning and maintenance

- You can clean the outside of your NovoPen 4 by wiping it with a damp cloth.
- Do not soak in water, wash or lubricate your NovoPen 4, this may damage it.
- Clean off dirt and dust with a dry cloth.

Important Things to Know

- Always keep a spare insulin delivery system in case your NovoPen 4 is lost or damaged.
- Keep your NovoPen 4, PenFill cartridges, and NovoFine needles out of the reach of children.
- Keep the NovoPen 4 away from areas where temperatures may get too hot or too cold such as a car or refrigerator.
- Use a separate insulin delivery device if you are using more than one type of insulin in PenFill cartridges.

Novo Nordisk is not responsible for harm due to using the NovoPen 4 with products other than PenFill 3 mL insulin cartridges, and NovoFine single use disposable needles.

Warranty

- Do not try to repair a faulty NovoPen 4.

If you think your NovoPen 4 is not working the right way, contact Novo Nordisk at 1-800-727-6500.

The LOT number of your NovoPen 4 is located on the mechanical part as illustrated in the inside cover.

For assistance or further information, write to:

Novo Nordisk Inc.
Customer Care
100 College Road West
Princeton, NJ 08540

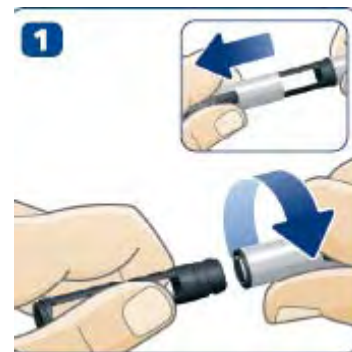
Or call: 1-800-727-6500

Quick Guide

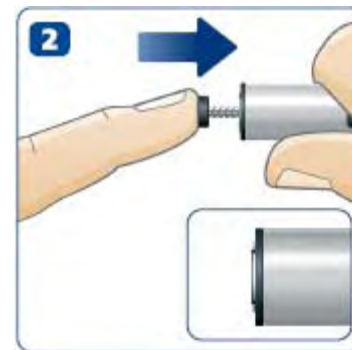


Preparing NovoPen 4

Pull off the cap. Unscrew and remove the cartridge holder from the mechanical part. See Figure 1.



Push in the piston rod, by pressing the piston rod head in until it stops and looks like Figure 2.



If you are using an insulin suspension (white and cloudy insulin), always mix (resuspend) it before use. See the NovoPen 4 Instruction Manual for details on how to mix (resuspend) the insulin.

Insert the PenFill cartridge into the cartridge holder, the color-coded cap goes in first. See Figure 3.



Screw NovoPen 4 together (see Figure 4).



Wipe the front rubber stopper with an alcohol swab and screw on a new NovoFine disposable needle. Pull off the outer and inner needle caps. Dispose of the needle caps. See Figure 5.

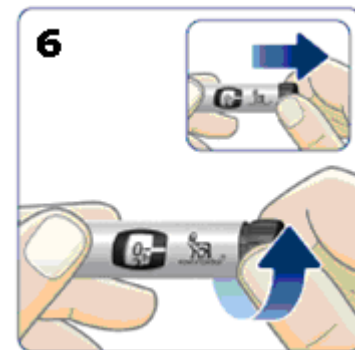


Do an “Air Shot” before each injection

Always do an airshot before each injection.

Pull out the dose button, if it is not already pulled out, and turn it to select:

- 4 units with a new PenFill cartridge
- OR
- 1 unit with a cartridge already in use



Hold your NovoPen 4 with the needle facing upwards.

Tap the cartridge holder gently with your finger a few times to make any air bubbles collect at the top of the cartridge. See Figure 7.



Press the dose button all the way in, until you hear or feel a click. The display will return to (0) See Figure 8.



A drop of insulin **must** appear at the needle tip. See Figure 9.

If you do not see a drop of insulin, repeat steps in Figures 5 to 7 until you see a drop of insulin. You may need to do this up to 6 times. If you do not see a drop of insulin after 6 times, do not use the NovoPen 4 and call Novo Nordisk at 1-800-727-6500.

Select your dose

Pull out the dose button, if it is not already pulled out, and turn the dose button until your needed dose lines up with the dose indicator. See Figure 10.

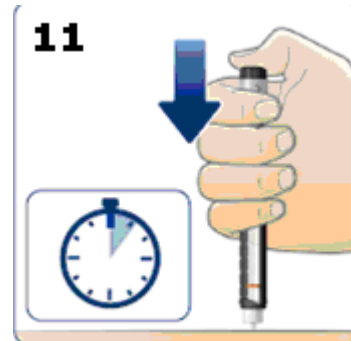
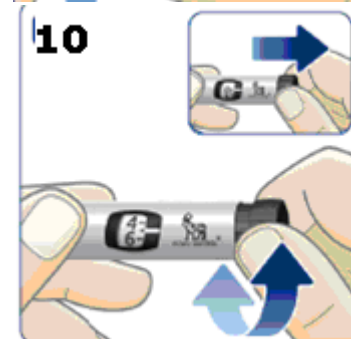
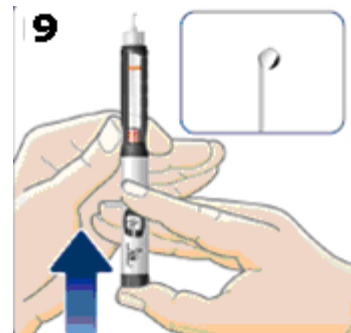
If you select a different dose than you need, turn the dose button until the correct dose lines up with the dose indicator.

Give your injection

Give the injection exactly as shown to you by your healthcare provider.

To inject, press the dose button completely in, until you hear or feel a click. Turning the dose button will not inject insulin. Leave the needle under the skin for at least 6 seconds. See Figure 11. Take the needle out of your skin, your selected dose has been given. Remove and dispose of the needle (follow the detailed instructions in the NovoPen 4 Instruction Manual).

Put the pen cap back on.



Front of carton:

List: XXXXXX

NovoPen® 4

Dial-A-Dose

Insulin Delivery Pen

CONTAINS ONE NOVOPEN 4

Designed for use with PenFill 3 mL cartridges and NovoFine disposable needles

Side Flap of Carton:

NovoPen® 4

Dial-A-Dose

Insulin Delivery Pen

List: XXXXXXXX

Lot

Side Flap of Carton:

NovoPen 4

Dial-A-Dose

Insulin Delivery Pen

Convenient Carrying Case Enclosed

The NovoPen 4 is designed for use with PenFill 3 mL cartridges and NovoFine disposable needles.

Needles and cartridges not included.

Back of Carton:

For information contact:

Novo Nordisk Inc.

Princeton, NJ 08540

www.novonordisk-us.com

Manufactured in Denmark by Novo Nordisk A/S
2880 Bagvaerd, Denmark

NovoPen 4 is covered under US Patent No. 5,693,027, US
Patent No. 6,663,602, US Patent No. 7,241,278, and other patents pending.

Novo Nordisk, NovoPen, NovoFine, NovoLog, PenFill, and Novolin are registered
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