

Pen User Manual

Sondelbay®

Teriparatide 20 micrograms (µg)/ 80 microlitres (µl) solution for injection, in pre-filled pen

Instructions for Use

Before using your new Sondelbay Pen, please read the front and back of these Instructions for Use completely. The back of this page contains troubleshooting and other important information.

Follow the instructions carefully when using the Sondelbay Pen. Also read the *Patient Information Leaflet* provided.

Do not share your Sondelbay Pen or your needles with others as infection or disease can spread from one person to another.

Your Sondelbay Pen contains 28 days of medicine.

Dispose of your Sondelbay Pen 28 days after your first injection, even if it is not completely empty.

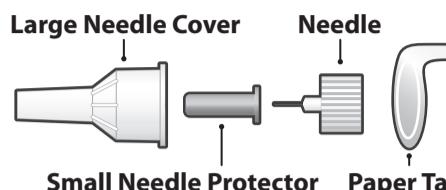
Do not inject more than one dose of Sondelbay on the same day.

Sondelbay Pen Parts

Pen Cap



Needles Not Included



Use with BD pen needles (31G or 32G; 4mm, 5mm or 8mm) manufactured by Becton, Dickinson and Company.

Ask your doctor or pharmacist which needle gauge (G) and length (mm) are best for you.

Use a new needle for every injection.

Injection Button Dose Setting Dial



Medicine Cartridge

Dose Setting Window



Dose Counter Window

Check the dose counter window to determine the number of doses remaining. The arrow points towards the number of doses remaining. A new pen should have 28 doses.

Black dots appearing in the dose counter window refer to the odd numbers of doses left in the pen.

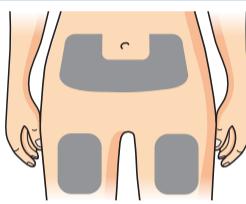
Do not use the pen if the dose counter reads '00' as this means there are no doses left.

Your Sondelbay Pen does not require priming.

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28
28

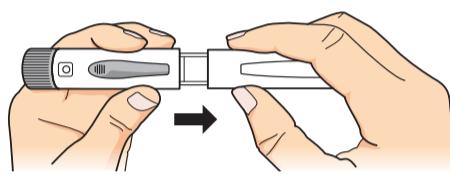
1

Prepare



Prepare the injection site (thigh or abdomen) as directed by your doctor or pharmacist.

- **Always** wash your hands before every injection.
- **Check** the pen label to make sure it is the correct medicine.
- **Check** the expiration date to make sure it has not passed.
- **Check** the dose counter window to make sure your pen has doses remaining. A new pen should have 28 doses in it.



Pull off the pen cap.

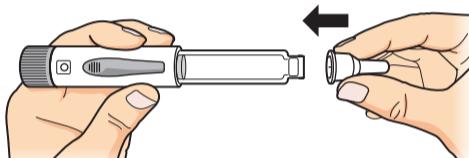
- **Check** that the pen, including the medicine cartridge, is not damaged.
- **Check** that the medicine is clear, colourless and free of particles.

2

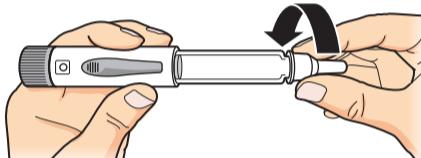
Attach new needle



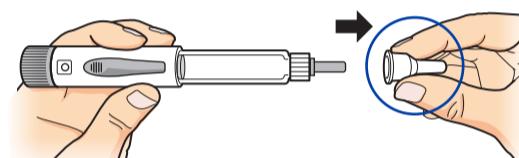
Obtain a new pen needle (see above). Pull off the paper tab.



Push the needle straight onto the medicine cartridge.



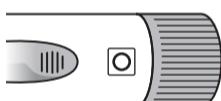
Screw on the needle until firmly attached.



Pull off the large needle cover and **save it**. You will need it to remove the needle after use.

3

Set dose



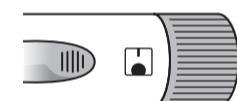
Check that an empty circle sign is in the dose setting window.



Turn the dose setting dial firmly clockwise, arrows will be seen in the dose setting window.



Keep turning all the way until you hear a click and see a filled circle sign in the dose setting window.



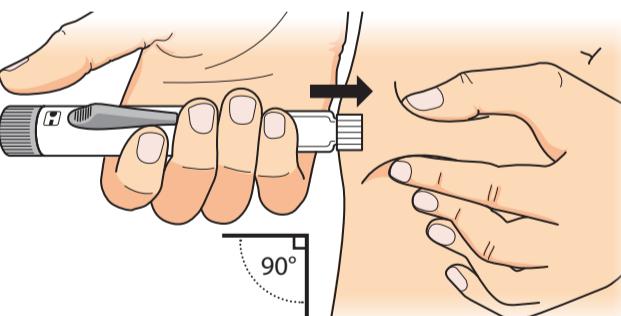
Let go of the dose setting dial. The filled circle with a bar above it will be seen in the dose setting window. This confirms you have set your dose.



Pull off the small needle protector and **dispose of it**.

4

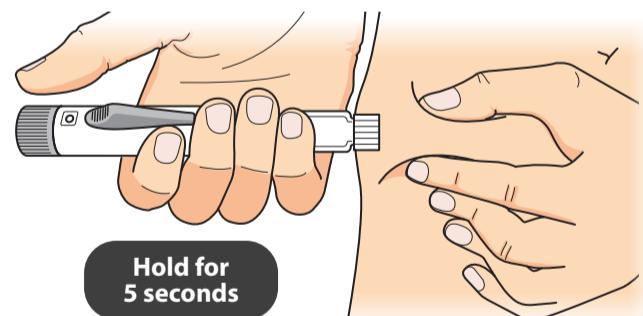
Inject dose



Gently hold a fold of skin from the thigh or abdomen. Insert the needle straight into the skin, making sure that the dose setting window is visible to you.



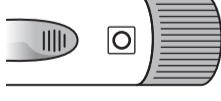
Keep the needle in the skin, **slide** the injection button until it stops. This will start your injection.



Keep the needle in the skin, wait until an empty circle sign appears in the dose setting window. Now count to 5 slowly then pull the needle from the skin.

5

Confirm dose



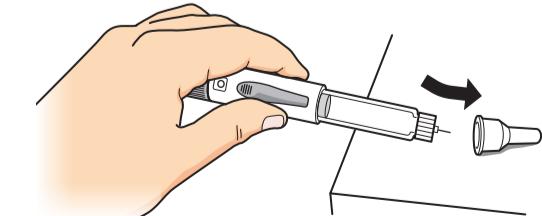
After you have completed the injection and removed the needle from the skin, **check** to make sure that the empty circle sign appears in the dose setting window.

If the empty circle sign **does not** appear in the dose setting window

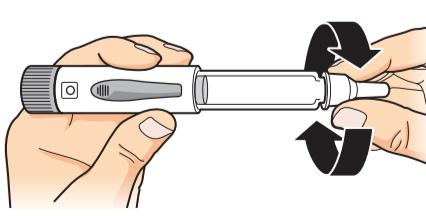
- **Do not inject a second time on the same day.**
- Instead, you must reset the pen. See Troubleshooting - Problem D.

6

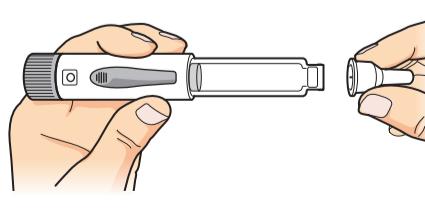
Remove needle



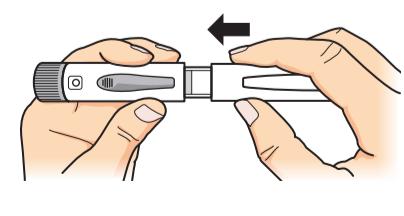
Put the large needle cover on the needle as shown above, then **push** it to secure it in place. To prevent needlestick injuries, **do not** try to re-attach the small needle protector or touch the needle.



Unscrew the needle from the pen by rotating the large needle cover counter-clockwise at least 5 times.



Pull off the needle and dispose of it as directed by your doctor or pharmacist.



Push the pen cap back on the pen firmly. Store the pen in the **refrigerator** immediately after use.

Troubleshooting

Problem

Solution

A.

I see an air bubble in my Sondelbay Pen.

A small air bubble will not affect your dose, nor will it harm you. You can continue to take your dose as usual.

B.

I cannot dial my dose.

1. Check the dose counter window and make sure that your Sondelbay Pen has at least one dose left. If you see 00 in the dose counter window, it means that there is no dose remaining in Sondelbay Pen. You may still see some medicine left in the cartridge, but it cannot be injected. You should use a new Sondelbay Pen to take your next dose.
2. If your Sondelbay Pen has at least one dose remaining, and you still cannot dial your dose, make sure you turn the dose setting dial clockwise until you hear a click and see a filled circle sign  in the dose setting window. Do not let go of the dose setting dial until you hear the click and see a filled circle sign, otherwise it will spring back to its original position. After the click, let go of the dose setting dial and you will see a filled circle sign with a bar on the top  in the dose setting window.

C.

I see a drop of medicine at the tip of the needle when I remove the small needle protector for injection.

A small drop of medicine at the tip of the needle will not affect your dose. Continue to take your dose as described in the Instructions for Use.

D.

The empty circle sign  did not appear in the dose setting window even after I pushed the injection button all the way and waited. What should I do?

You should reset your Sondelbay Pen by following the steps below:

1. **If you have already administered an injection, DO NOT inject yourself a second time on the same day.**
2. Remove the used needle by carefully re-attaching the large needle cover over the needle. **Do not** touch the needle. **Do not** try to re-attach the small needle protector. Unscrew the needle and dispose of it as directed by your doctor or pharmacist.
3. Attach a new needle, pull off the large needle cover and save it.
4. Point the small needle protector towards an empty container.
5. Pull off the small needle protector. Be careful, this may spray some medicine. It may also be possible that some medicine has already been squirted into the small needle protector. Dispose of the small needle protector.
6. You should now see the empty circle sign in the dose setting window. If you still cannot see it, please contact your doctor or pharmacist.
7. Put the large needle cover on the needle. **Do not** touch the needle. **Do not** try to re-attach the small needle protector. Unscrew the needle and dispose of it as directed by your doctor or pharmacist.
8. Put the pen cap back on the Sondelbay Pen, and place your Sondelbay Pen in the refrigerator.
9. Wash your hands.

You can prevent this problem by always using a NEW needle for every injection, and by sliding the injection button until it stops. Wait for the empty circle sign to appear then count to 5 slowly before removing the needle from the skin.

E.

How can I tell if my Sondelbay Pen works?

Your Sondelbay Pen is designed to inject the full dose every time you use it as per the Instructions for Use. The empty circle sign  is shown in the **dose setting window** following the injection to indicate that the full dose of medicine has been injected.

The **dose counting window** displays the number of doses remaining in the pen. This will count down by 1 each time an injection is given. This will also indicate that the pen is working.

Use a new needle for every injection to be sure your Sondelbay Pen will work properly.

F.

I cannot remove the needle from my Sondelbay Pen.

1. Put the large needle cover on the needle as shown in step 6 on the front page.
2. To unscrew the needle, push the needle onto the pen whilst rotating it counter-clockwise multiple times.
3. Pull off the needle and dispose of it as directed by your doctor or pharmacist.
4. If you still cannot get the needle off, ask someone to help you.

Cleaning and Storage

Cleaning your Sondelbay Pen:

- Wipe the outside of your Sondelbay Pen with a damp cloth.
- Do not place your Sondelbay Pen in water or clean it with any liquid.

Storing your Sondelbay Pen:

- Refrigerate your Sondelbay Pen immediately after every use.
- Do not store your Sondelbay Pen with a needle attached as this may cause air bubbles to form in the medicine cartridge.
- Always store your Sondelbay Pen with the pen cap on.
- Never store your Sondelbay Pen in the freezer.
- If the medicine has been frozen, throw the Sondelbay Pen away and use a new Sondelbay Pen.
- If your Sondelbay Pen has been left out of the refrigerator, do not throw it away. Place the pen back in the refrigerator and contact your doctor or pharmacist for their advice.

Disposal of Sondelbay Pen and Needles

Disposal of Sondelbay Pen:

- Dispose of your Sondelbay Pen 28 days after your first injection, even if it is not completely empty.
- Always remove the needle before disposing of your Sondelbay Pen.
- Ask your doctor or pharmacist how to dispose of your Sondelbay Pen.

Disposal of Needles:

- Put the used needles in a sharps container or a hard plastic container with a secure lid.
- Do not dispose of needles directly into your household waste.
- Do not recycle the filled sharps container.
- Ask your doctor or pharmacist how to dispose of the sharps container properly.
- These directions regarding needle handling are not intended to replace your local, healthcare professional's or institutional policies.

Other Important Notes

- Read and follow the directions in the *Patient Information Leaflet* for using the product.
- The Sondelbay Pen is not recommended for use by a blind or visually impaired person without the assistance of a person trained in the proper use of the device.
- Keep your Sondelbay Pen out of the sight and reach of children.
- Do not transfer the medicine into a syringe.
- Use a new needle for every injection.
- Check your Sondelbay Pen label to make sure you have the correct medicine and that it has not expired.
- Contact your doctor or pharmacist if you notice any of the following:
 - Your Sondelbay Pen appears damaged
 - Your medicine is NOT clear, colourless and free of particles
- Your Sondelbay Pen contains 28 days of medicine.
- Note down your first injection date. You should dispose of your Sondelbay Pen 28 days after your first injection.

Date of first use _____

Marketed by

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This user manual was last revised in Nov 2019