Sondelbay®
20 micrograms/80 microliters solution for injection in pre-filled pen
teriparatide

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Package leaflet: Information for the user

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▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. **What** Sondelbay **is and what it is used for**

Sondelbay contains the active substance teriparatide that is used to make the bones stronger, and to reduce the risk of fractures by stimulating bone formation.

Sondelbay is used to treat osteoporosis in adults. Osteoporosis is a disease that causes your bones to become thin and fragile. This disease is especially common in women after the menopause, but it can also occur in men. Osteoporosis is also common in patients receiving corticosteroids.

2. What you need to know before you use Sondelbay

Do not use Sondelbay
- if you are allergic to teriparatide or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from high calcium levels (pre-existing hypercalcaemia).
- if you suffer from serious kidney problems.
- if you have ever been diagnosed with bone cancer or other cancers that have spread (metastasised) to your bones.
- if you have certain bone diseases. If you have a bone disease, tell your doctor.
- if you have unexplained high levels of alkaline phosphatase in your blood, which means you might have Paget's disease of bone (disease with abnormal bone changes). If you are not sure, ask your doctor.
- if you have had radiation therapy involving your bones.
- if you are pregnant or breast-feeding.

Warnings and precautions
Sondelbay may cause an increase in the amount of calcium in your blood or urine.

Talk to your doctor or pharmacist before or while using Sondelbay:

- if you have continuing nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- if you suffer from kidney stones or have a history of kidney stones.
- if you suffer from kidney problems (moderate renal impairment).

Some patients get dizzy or get a fast heartbeat after the first few doses. For the first doses, inject Sondelbay where you can sit or lie down right away if you get dizzy.

The recommended treatment time of 24 months should not be exceeded.

Sondelbay should not be used in growing adults.

Children and adolescents
Sondelbay should not be used in children and adolescents (less than 18 years).

Other medicines and Sondelbay
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, because occasionally they may interact (e.g. digoxin/ digitalis, a medicine used to treat heart disease).

Pregnancy and breast-feeding
Do not use Sondelbay if you are pregnant or breast-feeding. If you are a woman of child-bearing potential, you should use effective methods of contraception during use of Sondelbay. If you become pregnant, Sondelbay should be discontinued. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Some patients may feel dizzy after injecting Sondelbay. If you feel dizzy you should not drive or use machines until you feel better.

Sondelbay contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

3. How to use Sondelbay

Always use this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 20 micrograms (in 80 microliters) given once daily by injection under the skin (subcutaneous injection) in the thigh or abdomen. To help you remember to use your medicine, inject it at about the same time each day.

Inject Sondelbay each day for as long as your doctor prescribes it for you. The total duration of treatment with Sondelbay should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.

Read the instructions for use, on how to use the Sondelbay pen.

Injection needles are not included with the pen. Use with pen needles (31G or 32G; 4 mm, 5 mm or 8 mm).

You should use your Sondelbay injection shortly after you take the pen out of the refrigeratoras described in the user manual. Put the pen back into the refrigerator immediately after you have used it.
Use a new injection needle for each injection and dispose of it after each use. Never store your pen with the needle attached. Never share your Sondelbay pen with others.

Your doctor may advise you to use Sondelbay with calcium and vitamin D. Your doctor will tell you how much you should take each day.

Sondelbay can be given with or without food.

If you use more Sondelbay than you should
If, by mistake, you have used more Sondelbay than you should, contact your doctor or pharmacist.

The effects of overdose that might be expected include nausea, vomiting, dizziness, and headache.

If you forget or cannot use Sondelbay at your usual time, use it as soon as possible on that day. Do not use a double dose to make up for a forgotten dose. Do not use more than one injection in the same day. Do not try to make up for a missed dose.

If you stop using Sondelbay
If you are considering stopping Sondelbay treatment, please discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Sondelbay.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effects are pain in limb (frequency is very common, may affect more than 1 in 10 people) and feeling sick, headache and dizziness (frequency is common). If you become dizzy (light-headed) after your injection, you should sit or lie down until you feel better. If you do not feel better, you should call a doctor before you continue treatment. Cases of fainting have been reported in association with teriparatide use.

If you experience discomfort such as redness of the skin, pain, swelling, itching, bruising or minor bleeding around the area of the injection (frequency is common), this should clear up in a few days or weeks. Otherwise tell your doctor as soon as possible.

Some patients may have experienced allergic reactions soon after injection, consisting of breathlessness, swelling of the face, rash and chest pain (frequency is rare). In rare cases, serious and potentially life-threatening allergic reactions including anaphylaxis can occur.

Other side effects include:
Common: may affect up to 1 in 10 people
- increase in blood cholesterol levels
- depression
- neuralgic pain in the leg
- feeling faint
- irregular heartbeats
- breathlessness
- increased sweating
- muscle cramps
- loss of energy
- tiredness
- chest pain
- low blood pressure
- heartburn (painful or burning sensation just below the breast bone)
- being sick(vomiting)
- a hernia of the tube that carries food to your stomach
- low haemoglobin or red blood cell count (anaemia)

Uncommon: may affect up to 1 in 100 people
- increased heart rate
- abnormal heart sound
- shortness of breath
- piles haemorrhoids
- accidental loss or leakage of urine
- increased need to pass water
- weight increase
- kidney stones
- pain in the muscles and pain in the joints. Some patients have experienced severe back cramps or pain which lead to hospitalisation.
- increase in blood calcium level
- increase in blood uric acid level
- increase in an enzyme called alkaline phosphatase.

Rare: may affect up to 1 in 1,000 people
- reduced kidney function, including renal failure
- swelling, mainly in the hands, feet and legs.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see contact details below). By reporting side effects you can help provide more information on the safety of this medicine.

For Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

For United Kingdom (Northern Ireland)
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA
Yellow Card in the Google Play or Apple App Store

5. How to store Sondelbay

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and pen after EXP. The expiry date refers to the last day of that month.

Sondelbay should be stored in a refrigerator (2^0C to 8^0C). Once opened, Sondelbay can be stored at temperature conditions up to 25°C for a maximum of 3 days when refrigeration is unavailable, after which it should be returned to the refrigerator and used within 28 days of the first injection. Discard Sondelbay, if it has been kept out of refrigerator up to 25°C for more than 3 days

Do not freeze Sondelbay. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use Sondelbay if it is, or has been, frozen.

Store in original package (i.e. outer carton) in order to protect from light.

Each pen should be disposed of after 28 days of first use, even if it is not completely empty.

Sondelbay contains a clear and colourless solution. Do not use Sondelbay if solid particles appear or if the solution is cloudy or coloured.

Do not transfer the medicine into a syringe.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use These measures will help to protect the environment.

6. Contents of the pack and other information

What Sondelbay contains
- The active substance is teriparatide. Each millilitre of the solution for injection contains 250 micrograms of teriparatide. Each dose of 80 microliters contains 20 micrograms of teriparatide. One pre-filled pen of 2.4 mL contains 600 micrograms of teriparatide.
- The other ingredients are glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol, and water for injections. In addition, hydrochloric acid and/or sodium hydroxide solution may have been added for pH adjustment(see section 2 “Sondelbay contains sodium”)..

What Sondelbay looks like and contents of the pack
Sondelbay is a colourless and clear solution. It is supplied in a cartridge contained in a pre-filled disposable pen. Each pre-filled pen contains 2.4 mL of solution for 28 doses. Sondelbay is available in packs containing one pre-filled pen or three pre-filled pens. Not all pack sizes may be available.

Marketing Authorisation Holder
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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu