

## Package leaflet: Information for the user

### CinnoPar® 20 micrograms/80 microliters solution for injection in pre-filled pen

#### Teriparatide

▼ 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.

250 mcg/mL, 2.4 mL

Solution for injection in pre-filled pen

**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 CinnoPar® is and what it is used for
2. What you need to know before you use CinnoPar®
3. How to use CinnoPar®
4. Possible side effects
5. How to store CinnoPar®
6. Content of the pack and other information

#### 1. What is CinnoPar® and what it is used for?

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

CinnoPar® 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 menopause, but it can also occur in men. Osteoporosis is also common in patients receiving corticosteroids.

#### 2. What you need to know before using CinnoPar®?

##### Do not use CinnoPar®

- 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

CinnoPar® may cause an increase in the amount of calcium in your blood or urine.

Talk to your doctor or pharmacist before or while using CinnoPar®:

- 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 CinnoPar® where you can sit or lie down right away if you get dizzy.

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

CinnoPar® should not be used in growing adults.

#### Children and adolescents

CinnoPar® should not be used in children and adolescents (less than 18 years).

#### Other medicines and CinnoPar®

Please 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 CinnoPar® 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 CinnoPar®. If you become pregnant, CinnoPar® should be discontinued. Ask your doctor or pharmacist for advice before taking any medicine.

#### Driving and using machines

Some patients may feel dizzy after injecting CinnoPar®. If you feel dizzy you should not drive or use machines until you feel better.

#### CinnoPar® 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 CinnoPar®

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 given once daily by injection under the skin (subcutaneous injection) in the thigh or abdomen. To help you remember to take your medicine, inject it at about the same time each day.

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

CinnoPar® can be injected at meal times.

Read the user manual overleaf for instructions on how to use the CinnoPar® pen.

Injection needles are not included with the pen. Compatible insulin needles can be used.

You should take your CinnoPar® injection shortly after you take the pen out of the refrigerator as 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 CinnoPar® pen with others.

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

CinnoPar® can be given with or without food.

#### If you use more CinnoPar® than you should

If, by mistake, you have used more CinnoPar® 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 take CinnoPar® at your usual time

Take it as soon as possible on that day.

Do not take a double dose to make up for a forgotten dose. Do not take more than one injection in the same day. Do not try to make up for a missed dose.

#### If you stop taking CinnoPar®

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

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 heart beats
- 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
- haemorrhoids (piles)
- 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 via the national reporting system.

By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. How to store CinnoPar®

- 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.
- CinnoPar® should be stored in a refrigerator (2 °C to 8 °C) at all times. You can use CinnoPar® for up to 28 days after the first injection, as long as the pen is stored in a refrigerator (2 °C to 8 °C).
- Do not freeze CinnoPar®. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use CinnoPar® if it is, or has been, frozen.
- Each pen should be properly disposed of after 28 days, even if it is not completely empty.
- CinnoPar® contains a clear and colourless solution. Do not use CinnoPar® if solid particles appear or if the solution is cloudy or coloured.
- 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 CinnoPar® contains

- The active substance is Teriparatide. Each millilitre of the solution for injection contains 250 micrograms of Teriparatide.
- The other ingredients are glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol and/or for injections. In addition, hydrochloric acid and/or sodium hydroxide solution may have been added for pH adjustment.

##### What CinnoPar® looks like and contents of the pack

CinnoPar® is a colourless and clear solution. It is supplied in a cartridge contained in a pre-filled disposable pen. Each pen contains 2.4 mL of solution enough for 28 doses. The pens are available in cartons containing one pen.

**This leaflet was last revised in 11/2020.**

## PEN USER MANUAL

### CinnoPar<sup>®</sup>

CinnoPar<sup>®</sup> 20 micrograms (µg)/ 80 microlitres solution for injection, in pre-filled pen

#### Instructions for use

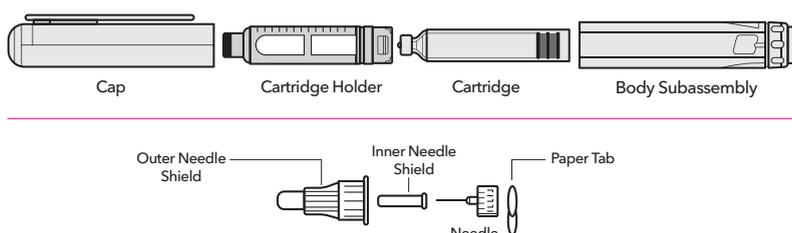
Before you use your new pen, please read the section Instructions for use completely. Follow the directions carefully when using the pen.

Also read the package leaflet provided.

Do not share your pen or your needles as this may risk transmission of infectious agents.

#### CinnoPar<sup>®</sup> parts\*

\* Injection needles are not included with the pen. Ask your doctor or pharmacist which needle gauge and length are best for you. Your pen contains 28 days of medicine.



Remove the pen from the refrigerator and wait until it reaches the room temperature.  
Prepare the injection site as directed by your doctor or pharmacist.

### Preparing for injection



- 1 Wash your hands thoroughly with soap and water and dry them.
- 2 Hold the pen with one hand. Remove the pen cap with your other hand. Check the CinnoPar<sup>®</sup> delivery device label to make sure you have the right medicine and that it has not expired. Do not use if the CinnoPar<sup>®</sup> delivery device looks damaged, if the medicine in the cartridge is not clear and colorless, or if it has particles in it.
- 3 Wipe the pen's septum with an alcohol swab.
- 4 Pull off the paper tab from the back of needle. While the outer needle shield still attached, place the needle straight onto the medicine cartridge. Screw on needle clockwise until firmly attached.
- 5 Pull off large needle cover and save it.
- 6 Pull off small needle protector and throw away.
- 7 In the first use, rotate the dose dialer until "2" aligns with the pointer in the dose displaying window.
- 8 Tap the cartridge gently with your finger to help air bubbles rise to the top. Some small bubbles may remain in the cartridge.
- 9 In the first use, rotate the dose dialer until "2" aligns with the pointer in the dose displaying window. Tap the cartridge gently with your finger to help air bubbles rise to the top. Some small bubbles may remain in the cartridge. Press the thumb button until "0" aligns with the pointer in the dose displaying window. Repeat steps 9 to 11 four times in total.

### Choosing the injection site

- 10 The areas that are shown with pink color (abdomen, thigh) are the best places to inject the medicine. It is recommended to rotate the injection site regularly.

### Adjusting the dose dialer

- 11 Rotate the dose dialer until the recommended number by your doctor appears in the dose displaying window. The usual daily dose of CinnoPar<sup>®</sup> is 20 micrograms given once daily which is equal to 8 number in dialer as it is indicated in figure 11.
  - Avoid unnecessary twisting of the dose dialer, it may impair the pen function.
  - If you turn dose dialer more than necessary (wrong dose dialed), simply turn the dose dialer backwards to set on the right number.
  - Do not press the button while setting the dose, since it leads to withdrawal of the medicine.
  - You cannot rotate the dose dialer to a value more than more than what is in the pen cartridge. Avoid turning the dose dialer by force. Throw away the pen or use the remaining units in the pen and complete your dose with a new pen.
  - Do not use the numbers written on the cartridge to make a judgement about the dose.
  - Never inject the whole content of the pen at once unless it is stated by your doctor.

### Injection

- 12 Disinfect the injection site on the skin with an alcoholic swab.
- 13 Gently hold a fold of skin on your thigh or abdomen to insert needle straight into skin.
- 14 Insert the needle straight into the skin at a 90-degree angle.
- 15 Press the button till number "0" appears in the dose displaying window. Do not touch the dose dialer with your fingers while pressing the button. This may prevent the injection.
- 16 Hold the button down and count slowly to 10 to ensure that the medicine has completely injected into the skin. Remove the needle out of your skin when you finished counting. If you saw drug liquids on the pen after you withdrew the pen, in the next injection, hold the needle in your skin for a longer time.

### After the Injection

- 17 Carefully replace the outer needle shield on the needle. Rotate the capped needle counterclockwise. Properly discard both the needle and the outer needle shield as directed by your health care professional. After injection, cover the injection site with dry cotton. Subcutaneous injection may cause transient pain or minor bruising in the injection area.
- 18 Replace the cap on the pen and keep it for up to 4 weeks in a refrigerator (2 - 8 °C).

## Cleaning and Storage

### Cleaning Your CinnoPar<sup>®</sup>

- Wipe the outside of the CinnoPar<sup>®</sup> with a damp cloth.
- Do not place the CinnoPar<sup>®</sup> in water, or wash or clean it with any liquid.

### Storing Your CinnoPar<sup>®</sup>

- Refrigerate the CinnoPar<sup>®</sup> immediately after every use. Read and follow the instructions in the Information for the Patient leaflet on how to store your pen.
- Do not store the CinnoPar<sup>®</sup> with a needle attached as this may cause air bubbles to form in the cartridge.
- Store the CinnoPar<sup>®</sup> with the white cap on.
- Never store the CinnoPar<sup>®</sup> in the freezer.
- If the medicine has been frozen, throw the device away and use a new CinnoPar<sup>®</sup>.
- If the CinnoPar<sup>®</sup> has been left out of the refrigerator, do not throw the pen away. Place the pen back in the refrigerator and contact your doctor or pharmacist.

## Disposal of Pen Needles and Device

### Disposal of Pen Needles and CinnoPar<sup>®</sup> Device

- Before disposing of the CinnoPar<sup>®</sup> device, be sure to remove the pen needle.
- Put used needles in a sharps container or a hard plastic container with a secure lid. Do not throw needles directly into your household waste.
- Do not recycle the filled sharps container.
- Ask your healthcare professional about options to dispose of the pen and the sharps container properly.
- The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.
- Dispose of the device 28 days after first use.

## Other Important Notes

- The CinnoPar<sup>®</sup> contains 28 days of medicine.
- Do not transfer the medicine into a syringe.
- Write down your first injection date on a calendar.
- Read and follow the instructions in the Information for the Patient leaflet for using the product.
- Check the CinnoPar<sup>®</sup> 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:
  - The CinnoPar<sup>®</sup> appears damaged
  - The solution is NOT clear, colourless and free of particles
- Use a new needle for each injection.
- During injection, you may hear one or more clicks - this is a normal device operation.
- The CinnoPar<sup>®</sup> is not recommended for use by the blind or visually impaired persons without the assistance of a person trained in the proper use of the device.
- Keep the CinnoPar<sup>®</sup> out of the sight and reach of children.

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