

Package leaflet: Information for the patient

Yorvipath®

Yorvipath 168 micrograms/0.56 mL solution for injection in pre-filled pen

Yorvipath 294 micrograms/0.98 mL solution for injection in pre-filled pen

Yorvipath 420 micrograms/1.4 mL solution for injection in pre-filled pen

palopegteriparatide

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

1. What Yorvipath is and what it is used for

Yorvipath contains the active substance palopegteriparatide. Palopegteriparatide is changed into teriparatide, also called parathyroid hormone (PTH), in the body. PTH naturally occurs in the body and is needed to keep the amount of calcium and phosphate in your body within the normal range.

Yorvipath is used to treat chronic hypoparathyroidism in adults. In people with hypoparathyroidism, the body produces no or too little PTH. Because of this, they cannot keep the levels of calcium and phosphate within a normal range, and this leads to the symptoms of the condition, such as muscle spasms, twitching, and tingling in your fingertips, toes and lips. Yorvipath replaces the missing PTH to help control the levels of calcium and phosphate.

2. What you need to know before you use Yorvipath

Do not use Yorvipath

- if you are allergic to palopegteriparatide or any of the other ingredients of this medicine (listed in section 6)
- if you have pseudohypoparathyroidism, a condition in which the body does not adequately respond to the parathyroid hormone produced by the body

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Yorvipath.

If you are treated with Yorvipath, you may have side effects related to low or high levels of calcium in your blood (see section 4 for more information). These effects are more likely to occur when starting treatment or when changing the dose. Your doctor will check your calcium levels (see 'Tests and checks' in section 3). You may be given medicines to treat or help prevent these side effects, or your doctor may change your dose.

High levels of calcium in your blood can cause problems if you take medicines that contain cardiac glycosides (such as digoxin or digitoxin) (see 'Other medicines and Yorvipath'). Your doctor will check your calcium (see 'Tests and checks' in section 3) and glycoside levels and monitor you for signs and symptoms.

If you take Yorvipath and have severe kidney or liver impairment, your doctor will check your calcium more often (see 'Tests and checks' in section 3).

Tell your doctor if you are at higher risk of a type of bone cancer called osteosarcoma. This is especially important:

- if you are having or have had radiation therapy to the skeleton
- if you have cancer of the bones or other cancer that has spread to your bones
- if you have a bone disease that increases your risk of developing osteosarcoma (for instance, if you have Paget's disease)
- if a blood test shows that you have unexplained increases in bone alkaline phosphatase

If you are at risk for bone fractures, your doctor will check you for osteoporosis.

Children and adolescents

Yorvipath should not be used in children or adolescents under 18 years old because it has not been studied in this age group.

Other medicines and Yorvipath

Tell your doctor, pharmacist or nurse if you are using, have recently used, or might use any other medicines. In particular, tell your doctor if you are using or have recently used any of the following:

- Heart medicines that contain cardiac glycosides (such as digoxin or digitoxin)
- Medicines used to treat osteoporosis, such as bisphosphonates, denosumab, or romosozumab
- Medicines that can affect calcium levels in your blood, such as diuretics ('water tablets', such as hydrochloride thiazide or furosemide), systemic corticosteroids (medicines used to treat inflammation), and lithium (medicine used to treat mood disorders)

Your doctor may need to adjust the dose of these medicines or the dose of Yorvipath.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

If you think you may be pregnant or are planning to have a baby, talk to your doctor. If you become pregnant during treatment, talk to your doctor immediately.

There is limited information on the safety of Yorvipath in pregnant women. Your doctor will decide whether you should be treated with Yorvipath during pregnancy. If you are pregnant or planning to become pregnant your doctor may check your calcium levels.

Breast-feeding

If you are breast-feeding or intend to breast-feed, ask your doctor for advice before using Yorvipath. Your doctor will decide whether you should be treated with Yorvipath during breast-feeding. If you are breast-feeding, your doctor may check your calcium levels.

Fertility

It is not known if Yorvipath has effects on fertility.

Driving and using machines

Yorvipath has no or very minor effects on your ability to drive or use machines. However, if you experience dizziness, fainting or light-headedness when standing up, do not drive or use machines until you feel better.

Yorvipath 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 Yorvipath

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

Yorvipath is given as an injection under the skin (subcutaneous injection). This means that it is injected with a short needle into the fatty tissue under the skin. The medicine should be injected into the belly (abdomen) or front of the thigh, and it is important to inject into a different area every day to help avoid damaging your skin. You can change between the left and right side of the belly and between the left and right front of the thigh.

Before you use the pen for the first time, your doctor, pharmacist or nurse will show you how to inject Yorvipath. Additional help with using Yorvipath is provided in the **instructions for use** at the end of this leaflet.

You should always use the pen as described in the instructions for use.

Starting, changing dose, and maintenance of Yorvipath

Your doctor will do a blood test to check your calcium and vitamin D levels before you start treatment with Yorvipath.

The recommended starting dose of Yorvipath is 18 micrograms once daily. Your doctor may advise you to gradually change your dose based on your response to the medicine, until you are using a dose that keeps the amount of calcium in your body within the normal range without the need for active vitamin D or therapeutic doses of calcium. Your doctor may tell you to keep taking daily calcium supplementation to meet dietary requirements. Your dose may be increased if at least 7 days have passed since your last change in dose. Your dose may be decreased no more often than every 3 days when the level of calcium in your body is too high.

Tests and checks

Your doctor will check how you respond to the treatment:

- 7 days after starting treatment and
- 7 to 14 days after your dose is changed

This will be done using tests to measure the level of calcium in your blood or urine. Your doctor may tell you to change the amount of calcium or vitamin D you take (in any form, including foods rich in calcium).

Directions for use

If your dose is above 30 micrograms per day:

- Administer two injections, one after the other, in separate injection sites.
- It is recommended to use a different Yorvipath pen for the second daily injection, even if the two pens have the same-coloured push button (same strength).
- The table below explains how to administer your dose. Check with your doctor if you are not sure.

If you use more Yorvipath than you should
Immediately contact your doctor or nurse and describe any symptoms you get.

An overdose may lead to high levels of calcium in the blood. Symptoms may include but are not limited to being sick (vomiting), dizziness, feeling thirsty, confusion, muscle weakness, and irregular heartbeat. See section 4 for more information.

If you forget to use Yorvipath

If you forget to inject a dose of Yorvipath, you can use the medicine as soon as you remember if less than 12 hours have passed. For example, if you normally inject the medicine at 8 o'clock in the morning, you can inject the missed dose before 8 o'clock in the evening.

If you only remember to use your dose within 12 hours of your next planned dose, skip the missed dose and continue injecting your next dose as you normally would. For example, if you remember at 10 o'clock in the evening that you forgot to inject Yorvipath, and your next dose is planned at 8 o'clock in the morning, you should not inject the missed dose.

Never take a second dose to make up for a missed dose.

If you stop using Yorvipath

Do not stop using Yorvipath without talking to your doctor. If you stop using Yorvipath the levels of calcium in your blood may decrease and you may develop the symptoms described below (see section 4).

If you have any further questions on the use of Yorvipath, ask your doctor or nurse.

4. Possible side effects

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

Some side effects could be considered serious
Common serious side effects (may affect up to 1 in 10 people):

- High levels of calcium in the blood (hypercalcaemia)
 - Symptoms may include, but are not limited to, being sick (vomiting), dizziness, feeling thirsty, confusion, muscle weakness, and irregular heartbeat.
- Hypercalcaemia is more likely to occur within the first 3 months of starting treatment or if you change your Yorvipath dose.
- Low levels of calcium in the blood (hypocalcaemia)
 - Symptoms may include, but are not limited to, tingling in your fingertips, toes and lips (paraesthesia), muscle spasms and cramps, oral numbness, and seizures.
 - Hypocalcaemia is more likely to occur if you stop taking Yorvipath for a short time or altogether, or if you change your Yorvipath dose.

Tell your doctor immediately if you experience any of the above-mentioned symptoms that may be a sign of these side effects. Your doctor will check your calcium levels. You may need to change your Yorvipath dose or stop the injections for a short time. You may be given medicines to treat or help prevent these side effects, or you may be asked to stop some of the medicines you are taking. These medicines include calcium or vitamin D. You may be asked to have some laboratory tests.

Other side effects include:

- Very common side effects** (may affect more than 1 in 10 people)
- Headache
 - Tingling in your fingertips, toes and lips (paraesthesia)
 - Feeling sick (nausea)
 - Feeling tired (fatigue)
 - Redness, bruising, pain, bleeding, rash or swelling where you injected the medicine (injection site reactions)

Common side effects (may affect up to 1 in 10 people)

- Feeling like your heart is fluttering or beating too fast (palpitations)
- Dizziness
- Feeling like you are about to faint (pre-syncope)
- Fainting (syncope)
- Dizziness, lightheadedness or fainting when you sit up or stand up (orthostatic hypotension)
- Dizziness, lightheadedness or fainting and increased heart rate when you sit up or stand up (postural orthostatic tachycardia syndrome)
- Sore mouth or sore throat (oropharyngeal pain)
- Diarrhoea
- Constipation
- Being sick (vomiting)
- Abdominal pain
- Abdominal discomfort
- Joint pain (arthralgia)
- Muscle pain (myalgia)
- Weakness (asthenia)
- Thirst
- Rash
- Skin reaction to sunlight (photosensitivity reaction)
- The need to pass urine at night (nocturia)
- Muscle twitching
- Pain in the muscles and bones (musculoskeletal pain)

Uncommon side effects (may affect up to 1 in 100 people)

- Chest pain
 - Chest discomfort
 - High blood pressure (hypertension)
- Not known** (Frequency cannot be estimated from the available data)
- The need to pass urine often (polyuria)
 - Bone density decreased

If you get any side effects or any symptoms that concern you, **tell your doctor or nurse**.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Yorvipath

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 after EXP. The expiry date refers to the last day of that month.

Before first use:

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Store in the original package with the pen cap on in order to protect from light.

After first use:

Store below 30 °C. Keep the pen cap on the pre-filled pen in order to protect from light.

Discard each pen 14 days after first use.

Do not use this medicine if you notice that the solution is cloudy, coloured, or has visible particles in it.

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 protect the environment.

6. Contents of the pack and other information

What Yorvipath contains

- The active substance is palopegteriparatide.
- The excipients are succinic acid, mannitol, metacresol, sodium hydroxide (see section 2, "Yorvipath contains sodium"), hydrochloric acid (for pH adjustment), and water for injections.

Yorvipath is a solution for subcutaneous injections in a pre-filled pen available in three presentations:

Yorvipath 168 micrograms/0.56 mL

Each pre-filled pen contains palopegteriparatide equivalent to 168 micrograms of PTH(1-34) in 0.56 mL of solvent. The concentration based on PTH(1-34) is 0.3 mg/mL.

Yorvipath 294 micrograms/0.98 mL

Each pre-filled pen contains palopegteriparatide equivalent to 294 micrograms of PTH(1-34) in 0.98 mL of solvent. The concentration based on PTH(1-34) is 0.3 mg/mL.

Yorvipath 420 micrograms/1.4 mL

Each pre-filled pen contains palopegteriparatide equivalent to 420 micrograms of PTH(1-34) in 1.4 mL of solvent. The concentration based on PTH(1-34) is 0.3 mg/mL.

What Yorvipath looks like and contents of the pack
Yorvipath is a clear and colourless solution free of particles for injection in a pre-filled pen. The outer carton contains two pre-filled pens and 30 disposable needles for 28 days of treatment (co-packaged in two inner cartons). Each inner carton contains one pre-filled pen and 15 needles for 14 days of treatment (14 needles for each day of treatment and 1 spare needle).

Strength colours are indicated on the outer and inner cartons, on the label and push button of the pre-filled pen, as follows:

Colour	Presentation
Blue	Yorvipath 168 micrograms/0.56 mL
Orange	Yorvipath 294 micrograms/0.98 mL
Burgundy	Yorvipath 420 micrograms/1.4 mL

Marketing Authorisation Holder

Ascendis Pharma Bone Diseases A/S
Tuborg Boulevard 12
DK-2900 Hellerup
Denmark

Manufacturer

Ascendis Pharma A/S
Tuborg Boulevard 12
DK-2900 Hellerup
Denmark

This leaflet was last revised in 04/2024.