

MEDICATION GUIDE
YORVIPATH® (YOR-vih-path)
(palopegteriparatide)
injection, for subcutaneous use

What is the most important information I should know about YORVIPATH?

YORVIPATH may cause serious side effects, including:

- **High levels of calcium in the blood (hypercalcemia).** YORVIPATH can cause some people to have higher blood calcium levels than normal. Your health care provider should check your blood calcium before you start and during your treatment with YORVIPATH. Tell your health care provider if you have nausea, vomiting, dizziness, feeling thirsty, confusion, muscle weakness, and irregular heartbeat. Hypercalcemia is more likely to occur within the first 3 months of starting YORVIPATH, but it may occur at any time.
- **Low levels of calcium in the blood (hypocalcemia).** People who stop using, miss, or change a dose of YORVIPATH may have an increased risk of low blood calcium levels, but hypocalcemia may occur at any time. Tell your health care provider if you have tingling in your fingertips, toes, lips or tongue, muscle spasms or cramps, oral numbness, depression, have problems thinking or remembering, abnormal heart rhythms, and seizures.
- **Possible bone cancer (osteosarcoma).** Tell your health care provider right away if you have pain in any areas of your body that does not go away or any new or unusual lumps or swelling under your skin that is tender to touch. These are some of the signs and symptoms of osteosarcoma and your health care provider may need to do further tests.

Tell your health care provider right away if you have any of these signs and symptoms of osteosarcoma, or high or low blood calcium levels.

See “**What are the possible side effects of YORVIPATH?**” for information about side effects.

What is YORVIPATH?

- YORVIPATH is a prescription medicine used to treat adults with low parathyroid hormone (PTH) (hypoparathyroidism).

It is not known if YORVIPATH is safe and effective in people who have been recently diagnosed with hypoparathyroidism after surgery.

It is not known if YORVIPATH is safe and effective if it is started in people with low levels of calcium in the blood.

It is not known if YORVIPATH is safe and effective in children.

YORVIPATH should not be used in children and young adults whose bones are still growing.

Who should not take YORVIPATH?

Do not use YORVIPATH if you:

- are allergic to palopegteriparatide or any of the other ingredients in YORVIPATH. See **the end of this Medication Guide for a complete list of ingredients in YORVIPATH.**

Before using YORVIPATH, tell your health care provider about all of your medical conditions, including if you:

- are at higher risk of a type of bone cancer called osteosarcoma. This is especially important:
 - if you have a bone disease that increases your risk of developing osteosarcoma (including if you have Paget’s disease).
 - if a blood test shows that you have unexplained increases in bone alkaline phosphatase.
 - if you have cancer of the bones or other cancer that has spread to your bones.
 - if you are having or have had radiation therapy to the skeleton.
 - if you are affected with a condition that runs in your family that can increase your chance of getting cancer in your bones.
- take medicines that contain digoxin.
- take medicines used to treat osteoporosis.
- take medicines that can affect calcium levels in your blood.
- are pregnant or plan to become pregnant. It is not known if YORVIPATH will harm your unborn baby.
 - Tell your health care provider if you become pregnant during treatment with YORVIPATH.
 - If you become pregnant while being treated with YORVIPATH, you are encouraged to enroll in the Pregnancy Safety Study. The purpose of the pregnancy safety study is to collect information about the health of you and your baby. Contact Ascendis Pharma at 1-844-442-7236 as soon as you learn that you are pregnant or ask your health care provider to contact them for you.

- are breastfeeding or plan to breastfeed. It is not known if YORVIPATH passes into your breast milk. Talk to your health care provider about the best way to feed your baby during treatment with YORVIPATH.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. YORVIPATH and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your health care provider and pharmacist when you get a new medicine.

How should I use YORVIPATH?

- Read the detailed **Instructions for Use** that comes with YORVIPATH.
- Use YORVIPATH exactly as your health care provider tells you to take it.
- Before you use YORVIPATH for the first time, a health care provider should show you how to use the pen the right way.
- Some people may feel dizzy, get a fast heartbeat, or feel light-headed right after injecting YORVIPATH. For the first few doses, give your injection of YORVIPATH in a place where you can sit or lie down right away if you get these symptoms. If your symptoms get worse or do not go away, contact your health care provider before you continue using YORVIPATH.
- **Do not** stop taking or change your dose of YORVIPATH unless your health care provider tells you to. The levels of calcium in your blood may change, and you may develop symptoms. See **“What are the possible side effects of YORVIPATH?”**
- Give no more than **1** YORVIPATH injection each day in your belly (abdomen) or in the front of the thigh just under your skin (subcutaneous). Inject into a different area each day to help avoid damaging your skin.
- Throw away each pen **14** days after first use.
- YORVIPATH is colorless. Do not use YORVIPATH if you notice that the solution is cloudy, colored, or has visible particles in it.
- Your health care provider should check your blood calcium level when you start and while you are using YORVIPATH. After you start YORVIPATH, your health care provider may change your doses of calcium and active vitamin D.
- If you miss a day or forget to inject your daily dose of YORVIPATH, you can inject the dose as soon as you remember if less than 12 hours have passed. If the dose has been missed by more than 12 hours, skip the missed dose and continue injecting your next dose as you normally would.

What are the possible side effects of YORVIPATH?

YORVIPATH may cause serious side effects:

- See **“What is the most important information I should know about YORVIPATH?”**
- **Allergic (hypersensitivity) reaction, including anaphylaxis.** Stop taking YORVIPATH and tell your health care provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction:

○ swelling of your face, lips, mouth, or tongue	○ fast heartbeat
○ breathing problems	○ itching
○ fainting, dizziness, feeling lightheaded (low blood pressure)	○ rash
	○ hives
- **Decrease in blood pressure when you change positions (orthostatic hypotension).** Some people may feel dizzy, get a fast heartbeat, or feel light-headed right after injecting YORVIPATH. For the first few doses, give your injection of YORVIPATH in a place where you can sit or lie down right away if you get these symptoms. If your symptoms get worse or do not go away, contact your health care provider before you continue using YORVIPATH.
- Digoxin toxicity if you are using digoxin and YORVIPATH at the same time. Tell your health care provider if you experience irregular heart rhythm, heart palpitations, confusion, loss of appetite, nausea, vomiting, diarrhea, or vision problems.

The most common side effects of YORVIPATH include injection site reactions, vasodilatory signs or symptoms such as a drop in blood pressure or lightheadedness when standing up, headache, diarrhea, back pain, high calcium levels, and sore throat.

These are not all of the possible side effects of YORVIPATH. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store YORVIPATH?

- Before first use, store YORVIPATH in a refrigerator between 36°F to 46°F (2°C to 8°C). **Do not** freeze. Store away from heat. Store in the package with the pen cap on in order to protect from light.

- After first use, store at room temperature below 86°F (30°C). Keep the pen cap on the prefilled pen in order to protect from light. Throw away each pen **14** days after first use.

Keep YORVIPATH and all medicines out of the reach of children.

General information about the safe and effective use of YORVIPATH.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use YORVIPATH for a condition for which it was not prescribed. Do not give YORVIPATH to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or health care provider for information about YORVIPATH that is written for health professionals.

What are the ingredients in YORVIPATH?

Active ingredient: palopegteriparatide

Inactive ingredients: mannitol, metacresol, sodium hydroxide, succinic acid, and water for injection.

Manufactured by: Ascendis Pharma Bone Diseases A/S, Denmark

YORVIPATH[®] is a registered trademark of Ascendis Pharma Group.

For more information, go to www.YORVIPATH.com or call 1-844-442-7236.