

Medication Guide
Teriparatide Injection, USP
(ter" i par' a tide)
for subcutaneous use

Read this Medication Guide before you start using teriparatide injection and each time you get a refill. There may be new information. Also, read the User Manual that comes with the teriparatide injection delivery device (pen) for information on how to use the device to inject your medicine the right way. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about teriparatide injection?

Possible bone cancer. During drug testing, the medicine in teriparatide injection caused some rats to develop a bone cancer called osteosarcoma. Studies in people have not shown that teriparatide injection increases your chance of getting osteosarcoma. There is little information about the chance of getting osteosarcoma in patients using teriparatide injection beyond 2 years.

What is teriparatide injection?

Teriparatide injection is a prescription medicine used to:

- treat postmenopausal women who have osteoporosis who are at high risk for having broken bones (fractures) or who cannot use other osteoporosis treatments. Teriparatide injection can lessen the chance of broken bones (fractures) in the spine and other bones in postmenopausal women with osteoporosis.
- increase the bone mass in men with primary or hypogonadal osteoporosis who are at high risk for having broken bones (fractures) or who cannot use other osteoporosis treatments.
- treat both men and women with osteoporosis due to use of glucocorticoid medicines, such as prednisone, for several months, who are at high risk for having broken bones (fractures) or who cannot use other osteoporosis treatments.

It is not known if teriparatide injection is safe and effective in children.

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

Who should not use teriparatide injection?

Do not use teriparatide injection if you:

- are allergic to any of the ingredients in teriparatide injection. See the end of this Medication Guide for a complete list of the ingredients in teriparatide injection.

Symptoms of a serious allergic reaction of teriparatide injection may include swelling of the face, lips, tongue or throat that may cause difficulty in breathing or swallowing. Call your healthcare provider right away or get emergency medical help if you get any of these symptoms.

What should I tell my healthcare provider before using teriparatide injection?

Before you use teriparatide injection, tell your healthcare provider about all of your medical conditions, including if you:

- have a certain bone disease called Paget's disease or other bone disease.
- have bone cancer or have had a history of bone cancer.
- are a young adult whose bones are still growing.
- have had radiation therapy.
- are affected with a condition that runs in your family that can increase your chance of getting cancer in your bones.
- have or have had too much calcium in your blood (hypercalcemia).
- have or have had a skin condition with painful sores or wounds caused by too much calcium.
- have or have had kidney stones.
- take medicines that contain digoxin.
- are pregnant or plan to become pregnant. It is not known if teriparatide injection will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if teriparatide injection passes into your breastmilk. You should not breastfeed while taking teriparatide injection.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use teriparatide injection?

- Read the detailed Instructions for Use (User Manual) included with your teriparatide injection delivery device.
- Use teriparatide injection exactly as your healthcare provider tells you to. Your healthcare provider will tell you how much teriparatide injection to use and when to use it.
- Before you try to inject teriparatide injection yourself, a healthcare provider should teach you how to use the teriparatide injection delivery device to give your injection the right way.
- Inject teriparatide injection 1 time each day in your thigh or abdomen (lower stomach area). Do not inject into a vein or a muscle. Talk to a healthcare provider about how to rotate injection sites.
- The teriparatide injection delivery device has enough medicine for 28 days. It is set to give a 20-microgram dose of medicine each day. Do not inject all the medicine in the teriparatide injection delivery device at any one time.
- Do not transfer the medicine from the teriparatide injection delivery device to a syringe. This can result in taking the wrong dose of teriparatide injection. If you do not have pen needles to use with your teriparatide injection delivery device, talk with your healthcare provider.
- Teriparatide injection should look clear and colorless. Do not use teriparatide injection if it has particles in it, or if it is cloudy or colored.
- Inject teriparatide injection right away after you take the delivery device out of the refrigerator.
- After each use, safely remove the needle, recap the delivery device, and put it back in the refrigerator right away.
- When you inject the first few doses of teriparatide injection, make sure you are in a place where you can sit or lie down right away in case you feel dizzy or have an abnormal heartbeat after the injection.
- Do not take more than 1 injection in the same day.
- Do not share your teriparatide injection delivery device with other people.
- If you take more teriparatide injection than prescribed, call your healthcare provider. If you take too much teriparatide injection, you may have nausea, vomiting, weakness, or dizziness.
- You should not use teriparatide injection for more than 2 years over your lifetime unless your healthcare provider finds that you need longer treatment because you have a high chance of breaking your bones.

If your healthcare provider recommends calcium and vitamin D supplements, you can take them at the same time you take teriparatide injection.

What are the possible side effects of teriparatide injection?

Teriparatide injection may cause serious side effects including:

- See **“What is the most important information I should know about teriparatide injection?”**
- **Bone cancer (osteosarcoma):** Tell your healthcare provider right away if you have pain in your bones, 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.
- **Increased calcium in your blood.** Tell your healthcare provider if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- **Worsening of your kidney stones.** If you have or have had kidney stones your healthcare provider may check the calcium levels in your urine while you use teriparatide injection to see if there is worsening of this condition.
- **Decrease in blood pressure when you change positions.** Some people may feel dizzy, get a fast heartbeat, or feel light-headed right after the first few doses of teriparatide injection. This usually happens within 4 hours of taking teriparatide injection and goes away within a few hours. For the first few doses, give your injections of teriparatide injection 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 healthcare provider before you continue using teriparatide injection.

The most common side effects of teriparatide injection include:

- pain
- nausea

- joint aches

These are not all the possible side effects of teriparatide injection. For more information, ask your healthcare provider or pharmacist.

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 teriparatide injection?

- Store teriparatide injection in the refrigerator between 36°F to 46°F (2°C to 8°C) until ready to use. Use teriparatide injection right away after you remove it from the refrigerator.
- Do not freeze the teriparatide injection delivery device. Do not use teriparatide injection if it has been frozen.
- Throw away the teriparatide injection delivery device after 28 days even if it has medicine in it (see the User Manual).
- Do not use teriparatide injection after the expiration date printed on the delivery device and packaging.
- Recap teriparatide injection when not in use to protect it from physical damage and light.

Keep teriparatide injection and all medicines out of the reach of children.

General information about the safe and effective use of teriparatide injection.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use teriparatide injection for a condition for which it was not prescribed. Do not give teriparatide injection to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about teriparatide injection that is written for health professionals.

What are the ingredients in teriparatide injection?

Active ingredient: teriparatide

Inactive ingredients: glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol, and water for injection. In addition, hydrochloric acid solution 10% and/or sodium hydroxide solution 10% may have been added to adjust the product to pH 4.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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