

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **OSNUVO**TM

teriparatide (rDNA origin) injection

Read this carefully before you start taking **Osnuvo** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Osnuvo**.

Osnuvo is a biosimilar biologic drug (biosimilar) to the reference biologic drug Forteo^{®3}. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

What is Osnuvo used for?

- Osnuvo is a prescription medicine used to treat osteoporosis by forming new bone. Osnuvo is approved for use in both men and postmenopausal women with severe osteoporosis. Osnuvo is also approved for use in both men and women with severe osteoporosis related to use of corticosteroid medicines, such as prednisone, who are at high risk for having broken bones (fractures). These include men and women with either a history of broken bones or those with a low bone mineral density (BMD).

How does Osnuvo work?

Osnuvo builds new bone faster than the old bone is lost. Your bones become stronger as you continue to use Osnuvo, and your risk for fracture will be reduced.

What are the ingredients in Osnuvo?

Medicinal ingredient: teriparatide (rDNA origin)

Non-medicinal ingredients: Glacial acetic acid, Mannitol, Metacresol, Hydrochloric acid (for pH adjustment), Sodium acetate trihydrate, Sodium hydroxide (for pH adjustment), Water for injections.

Osnuvo comes in the following dosage forms:

Teriparatide (rDNA origin) is supplied as a sterile solution for subcutaneous injection in a glass cartridge containing 2.4 mL of solution, in boxes of 1 or 3 cartridges. Not all pack sizes may be marketed.

Each cartridge contains 28 doses of 20 micrograms (per 80 microliters).

Each mL of solution contains 250 mcg teriparatide (rDNA origin).

To take Osnuvo, the cartridge needs to be inserted into a dedicated injection “pen”. See “How to Take Osnuvo”.

³ Forteo is a registered trademark of Eli Lilly and Company.

Do not use Osnuvo if you:

- have had an allergic reaction to teriparatide or one of its ingredients.
- suffer from high blood calcium level (pre-existing hypercalcemia).
- suffer from kidney problems (severe renal impairment).
- have other bone diseases.
- have high levels of alkaline phosphatase.
- have had radiation therapy involving your bones.
- have ever been diagnosed with bone cancer or other cancers that have spread (metastasized) to your bones.
- are a child or growing adult.
- are pregnant or breast-feeding.
- have trouble injecting yourself and do not have someone who can help you.

Only take Osnuvo if your doctor has prescribed it for you.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Osnuvo. Talk about any health conditions or problems you may have, including if you:

- are taking digoxin, which is prescribed for heart failure, fast heart rate, or irregular heart rhythm.
- currently have or recently had kidney problems.
- are experiencing symptoms associated with low blood pressure before or after injection. You should not drive or operate machinery until these symptoms go away.

Other warnings you should know:

- You may experience increased levels of calcium in your blood temporarily. Contact your healthcare professional if you experience nausea, vomiting, constipation, lethargy, or muscle weakness that do not go away.
- As part of drug testing, teriparatide (rDNA origin), the active ingredient in Osnuvo, was given to rats for a significant part of their lifetime. In these studies, teriparatide (rDNA origin) caused some rats to develop osteosarcoma, a bone cancer. The potential to cause osteosarcoma in rats was increased with higher doses and longer periods of treatment. Osteosarcoma in humans is a serious but very rare cancer. Osteosarcoma occurs in about 4 out of every million people each year. None of the patients in the clinical trials developed osteosarcomas. Osteosarcoma has been rarely reported in people who took prescription teriparatide (rDNA origin). You should discuss any safety concerns you have about the use of Osnuvo with your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines when you start taking Osnuvo, and if you start taking a new medicine after you start Osnuvo treatment. Tell them about all medicines you get with prescriptions and without prescriptions. Your health professional(s) need this information to help keep you from taking a combination of products that may harm you.

Ask your health professional about options that may help your treatment with Osnuvo, such as:

- taking calcium and/or vitamin D supplements,
- doing weight-bearing exercise, and
- stopping or reducing cigarette smoking, alcohol or coffee.

How to take Osnuvo:

- Osnuvo cartridges are designed to be used with the reusable, multidose medicine delivery system (injector pen) with compatible pen needles. The injector pen is dedicated to Osnuvo. The injector pen and injection needles are not included with Osnuvo.
- Before the first use of Osnuvo, you should consult the detailed instructions for use of your injector pen to ensure proper preparation.
- Use a new injection needle for each injection to prevent contamination and dispose of it after each use. Never store your injector pen with the needle attached.
- Never share your injector pen with others.
- Do not refill the cartridge. Do not transfer the medicine into a syringe. Do not use your injector pen to inject any other medicine (e.g. insulin). The pen is customized for use with Osnuvo only.
- You should use your Osnuvo shortly after you take the cartridge/injector pen with inserted cartridge out of the refrigerator. Put the injector pen with inserted cartridge back into the refrigerator immediately after you have used it.
- Do not remove the cartridge from the pen after each usage. It must remain in the cartridge sleeve during the whole 28-day treatment period.
- The injection may be given into the thigh or abdomen.
- Osnuvo can be taken at any time of day. To help you remember to take Osnuvo, take it at about the same time each day (for example, at bedtime).
- Osnuvo can be taken with or without food or drink.
- Osnuvo is a sterile, colorless, clear solution. Do not use if solid particles appear or if the solution is cloudy or coloured.
- Osnuvo should never be used beyond the expiry date indicated on the label.

Getting the injector pen ready to use

To ensure the correct administration of Osnuvo always read the injector pen Instructions for Use, which is included in the carton of the pen.

- Wash your hands before handling the cartridge or pen.
- Check the expiry date on the cartridge label before inserting the cartridge into the pen. Make sure that there is at least 1 month remaining before its expiry date. Insert the cartridge into the pen before the first use as detailed in the injector pen instructions. Write down the batch (Lot) number of each cartridge and its first injection date on a calendar. The date of first injection should also be recorded on the outer carton of Osnuvo (see the provided space on the box: {First use:}).
- After inserting a new cartridge and before the first injection from this cartridge, prime the pen according to the instructions provided. Do not prime again after the first dose.

Injecting Osnuvo

Before you inject Osnuvo, clean your skin where you intend to inject (thigh or abdomen) as instructed by your doctor.

- Gently hold a fold of cleansed skin and insert the needle straight into the skin. Press the push button and hold it pressed in until the dose indication has returned to the start position.
- After your injection, leave the needle in the skin for six seconds to make sure that you receive the whole dose.
- As soon as you have finished the injection, attach the outer needle protective cap to the pen needle and screw the cap counter-clockwise to remove the pen needle. This will keep the remaining Osnuvo sterile and prevent leaking from the pen. It will also stop air from going back into the cartridge and the needle from clogging.
- Dispose of the needle safely, as per your local waste management program.
- Once the needle removed, replace the cap on your pen. Leave the cartridge in the pen.
- If you feel lightheaded after injection, sit or lie down until the symptoms resolve. If symptoms don't go away or become worse, contact your health professional before continuing treatment.

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

Usual dose:

Take 20 mcg once daily for as long as your doctor prescribes it for you. The dose is preset using the injector pen. See "How to take Osnuvo".

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

Overdose:

Taking too much Osnuvo may cause nausea, vomiting, dizziness, and headache.

If you think you, or a person you are caring for, have taken too much Osnuvo, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget or are unable to take Osnuvo at your usual time, take 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.

What are possible side effects from using Osnuvo?

These are not all the possible side effects you may have when taking Osnuvo. If you experience any side effects not listed here, tell your healthcare professional.

- Most of the side effects of Osnuvo are mild. The most common side effects of Teriparatide are dizziness, nausea, pain in and around joints, and leg cramps.
- If you become dizzy do not drive or operate machinery; you should sit or lie down until the symptoms go away. If symptoms continue or get worse, you should call a health professional before continuing treatment.

- Contact your health professional 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 have any problems or questions while taking Osnuvo, ask your health professional for more information.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store the cartridge in a refrigerator (2°C to 8°C) at all times. You can use Osnuvo for up to 28 days after the first injection, as long as the cartridge/pen with the cartridge inserted is stored in a refrigerator (2 °C to 8 °C).
- Do not freeze Osnuvo. Avoid placing the cartridge close to the ice compartment of the refrigerator to prevent freezing. Do not use Osnuvo if it is, or has been, frozen.
- Each cartridge should be properly disposed of after 28 days of first use, even if it is not completely empty.
- Do not use this medicine after the expiry date which is stated on the carton and the cartridge after “EXP”. The expiry date refers to the last day of that month.
- Keep the cartridge in the outer carton in order to protect from light until it is inserted in the injector pen.
- Osnuvo contains a clear and colourless solution. Do not use Osnuvo 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 protect the environment.

Keep out of reach and sight of children.

If you want more information about Osnuvo:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer’s website www.avirpharma.com, or by calling 1-800-363-7988.

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