

UNDERSTANDING OSNUVO®

Your Guide

 Pr **Osnuvo**®
teriparatide (rDNA origin) injection

ABOUT OSNUVO®

Osnuvo® (teriparatide (rDNA origin) injection) is used to treat osteoporosis by forming new bone. Osnuvo® is for use in:

- Men and postmenopausal women with severe osteoporosis, and;
- Men and women with severe osteoporosis related to the use of corticosteroid medicines, such as prednisone, who are at high risk for fractures.

These include men and women with either a history of fractures or those with a low bone mineral density (BMD).

WHAT IS THE USUAL DOSE FOR OSNUVO®?

Osnuvo® is a subcutaneous self-injected medication (20 mcg) that should be taken once daily for as long as your doctor prescribes it for you.

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

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.

For more information about Osnuvo®, talk to your healthcare professional.

WHAT IS OSTEOPOROSIS?

Bone is living tissue that is constantly changing in a process called remodeling, which means old bone tissue is removed and replaced with new bone tissue.

Osteoporosis causes bones to become weak and brittle.

HOW OSNUVO® WORKS

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

BEFORE YOU START TAKING OSNUVO®

Do not use Osnuvo® if you:

- have had an allergic reaction to teriparatide (rDNA origin) injection 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.

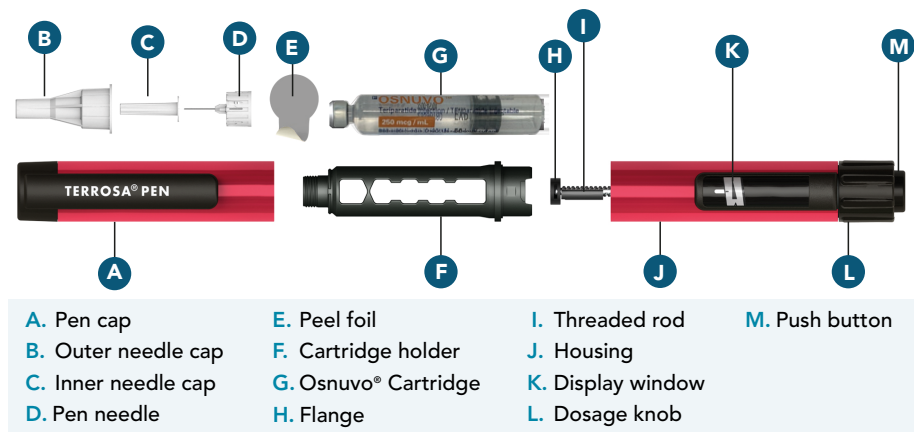
To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Osnuvo®. Talk about any health conditions or problems you may have, including if you:

- are taking digoxin, 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.

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.

THE TERROSA® INJECTOR PEN

Before the first use of Osnuvo®, consult the detailed instructions for use of your TERROSA® injector pen to ensure proper preparation.



The display window on the side of your pen (K) will indicate when your pen is primed and when it is ready to inject.



START POSITION

This icon indicates the start position before priming or setting your dose.



PRIMING / FUNCTIONAL TEST

This droplet sign indicates that your pen is ready to be tested/primed. **NOTE: DO NOT repeat "priming/functional test" before each and every daily injection. Otherwise, you will not have enough Osnuvo® for 28 days.**



SETTING THE DOSE AND INJECTION

The arrow image will appear aligned with the indicator stripe when your full normal daily dose is ready for your daily injection (80 microlitres).

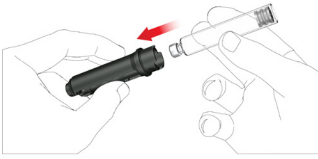
Osnuvo® was developed to be administered using the TERROSA® pen and the compatible injection needles.*

* The injector pen and injection needles are not included with Osnuvo®.

IMPORTANT:

- The injector pen is dedicated to Osnuvo® and should be used during the entire duration of your treatment. DO NOT discard until your treatment is over.
- Never share your injector pen with others.
- Do not use your TERROSA® injector pen to inject any other medicine. (e.g. insulin)
- You will receive your TERROSA® pen at the same time as your Osnuvo® prescription at the pharmacy. If you have any questions, contact the Patient Care Program at 1-833-455-0972 or email osnuvoair@iqvia.com.

THE OSNUVO® CARTRIDGE



- Osnuvo® is supplied in a box containing one glass cartridge. Each cartridge has enough medicine for 28 days. It is set to deliver a 20-microgram dose of medicine each day.
- The Osnuvo® cartridge needs to be inserted into the dedicated, reusable, multidose TERROSA® pen.
- Osnuvo® **MUST NOT** be used with any other injection device.
- Osnuvo® is a sterile, colorless, clear solution. Do not use if solid particles appear or if the solution is cloudy or coloured.
- Do not refill the cartridge.
- Do not transfer the medicine into a syringe.

COMPATIBLE INJECTION NEEDLES

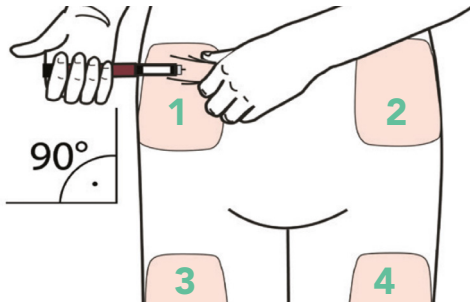
- Use needles with a gauge of 29G to 31G and a length between 5 mm and 12.7 mm.
- Use a new injection needle for each injection to help prevent contamination and dispose of it after each use.

If you are unsure about which needles to purchase, call the Osnuvo® Patient Care program at 1-833-455-0972 or speak to your pharmacist.

HOW TO TAKE OSNUVO®

Osnuvo® can be taken at any time of day, with or without food or beverages. Once you establish a specific time to administer Osnuvo®, take it around the same time each day.

- Before the first use of Osnuvo®, consult the detailed instructions for your injector pen that are included in the TERROSA® pen box. You can also contact your Osnuvo® Patient Care Program specialist to get more information on injection training.
- Use Osnuvo® shortly after you take the injector pen with inserted cartridge out of the refrigerator. Put the injector pen with inserted cartridge back into the refrigerator immediately after use.
- 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.
- Do not remove the cartridge from the pen after each use. It must remain in the cartridge sleeve during the whole 28-day treatment period.
- The injection may be given into four (4) areas of the body: left thigh, right thigh, left abdomen, right abdomen.
- Do not stop using Osnuvo® without consulting your doctor.
- Osnuvo® should never be used beyond the expiry date indicated on the label.



POTENTIAL SIDE EFFECTS

WHAT ARE POSSIBLE SIDE EFFECTS OF OSNUVO®

Most of the side effects associated with Osnuvo® are mild. The most common side effects are:

- Dizziness
- Pain in and around joints
- Nausea
- 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.

OTHER WARNINGS YOU SHOULD KNOW ABOUT

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.

These are not all the possible side effects you may experience when taking Osnuvo®. If you experience a troublesome symptom or side effect that interferes with your daily activities, talk to your healthcare professional.

INJECTION-SITE REACTIONS

If you experience an injection-site reaction (i.e. redness), review the tips provided below to help manage the situation.

TIPS:

- If you are cleaning your skin with alcohol prior to injection, let the alcohol air dry for 60 seconds to reduce stinging.
- Make sure to rotate injection sites and that the injection depth is correct.

Consult with your nurse, pharmacist or doctor to get additional suggestions to help manage reactions.

HOW TO STORE OSNUVO® AND CARE FOR YOUR TERROSA® INJECTOR PEN

- Store the cartridge in a refrigerator (2°C to 8°C) at all times.
- Once cartridge is inserted into the TERROSA® pen, store the TERROSA® pen with inserted cartridge in the refrigerator, between 2 °C and 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).
 - 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 use.
 - 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.
- DO NOT store the TERROSA® pen with a needle attached.
- Do not freeze Osnuvo®. Do not use Osnuvo® if it is or has been frozen.
- Do not use the 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.
- Store the cartridge in its outer box to protect it from light until you insert it into the injector pen.
- Keep your TERROSA® pen, cartridges and pen needles out of sight and reach of children.

HOW TO DISPOSE OF YOUR OSNUVO® CARTRIDGE AND NEEDLES

- Each cartridge should be properly disposed of after 28 days of use, even if it is not completely empty.
- 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.

Refer to the Terrosa® injector pen instructions for use leaflet for complete care, storage, and disposal instructions.

TIPS TO HELP WITH YOUR OSNUVO® THERAPY

HELPING YOU STAY ON TRACK WITH YOUR INJECTIONS

It is important to take Osnuvo® at the same time every day. However, forgetting to take your medication can happen. Here are some tips to help you remember to take Osnuvo®:



- Make Osnuvo® part of your daily routine, like brushing your teeth or going to bed.



- Mark your calendar on the first day you use Osnuvo® to remind you to change the cartridge every 28 days.

WHAT IF I MISS A 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 DO I DO IF I TAKE TOO MUCH OSNUVO®?

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.

DIET AND EXERCISE

Eating a healthy diet and exercising regularly can help improve bone health.

- A diet rich in calcium and vitamin D can help improve bone health.
- Weight-bearing activities that put stress on your bones like walking, running or strength training can help strengthen bones and slow bone loss.



RESOURCES

For more information on osteoporosis and how to manage your condition, the following resources are available:

Osteoporosis Canada

<https://www.osteoporosis.ca/>

Public Health Agency of Canada, Osteoporosis

<https://www.canada.ca/en/public-health.html>

THE OSNUVO® PATIENT CARE PROGRAM IS THERE FOR YOU

The Osnuvo® Patient Care Program offers support throughout your Osnuvo® treatment journey. The program is free and is designed to help you manage your condition and treatment. Here are some of the services offered by the program:



Reimbursement Navigation

Our reimbursement experts can help you understand your insurance coverage and reimbursement options.



Injection Training & Education

The program offers injection training resources as well as assistance from a trained healthcare professional.



Financial Assistance

Our program specialists conduct individual assessments and explore financial solutions to help manage treatment reimbursement.*

For more information about the Osnuvo® Patient Care Program, call us at 1-833-455-0972 or email us at osnuvoavir@iqvia.com.

*For those who are eligible



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