

HELP ALONG THE WAY IN YOUR FIGHT FOR STRONGER BONES

Get to know STOBOCLO, an FDA-approved biosimilar to Prolia[®] (denosumab)

STOBOCLO is a prescription medicine used to:

- Treat osteoporosis in women after menopause who are at high risk for fracture or who cannot use or haven't responded well to other osteoporosis medicines.
- Increase bone mass in men with osteoporosis who are at high risk for fracture.
- Treat osteoporosis in men and women who will be taking corticosteroid medicines (such as prednisone) for at least 6 months and are at high risk for fracture.
- Treat bone loss in men who are at high risk for fracture receiving certain treatments for prostate cancer that has not spread to other parts of the body.
- Treat bone loss in women who are at high risk for fracture receiving certain treatments for breast cancer that has not spread to other parts of the body.

It is not known if STOBOCLO is safe and effective in children. STOBOCLO is not approved for use in children.

IMPORTANT SAFETY INFORMATION

If you receive STOBOCLO, you should not receive other denosumab products at the same time.

FDA, Food and Drug Administration.

What is STOBOCLO?

STOBOCLO is a prescription biosimilar

STOBOCLO is a biosimilar of Prolia® (denosumab). Biosimilar means that:



- The biologic product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product
- There are no clinically meaningful differences in how it works or in how safe it is compared to the reference product

A biosimilar is typically more affordable than the reference product.

Since STOBOCLO is a biosimilar of Prolia, it can be used instead of Prolia.

Like Prolia, STOBOCLO works to strengthen bones and reduce the risk of fractures



Osteoporosis is a condition where bones become weaker and less dense, which can lead to an increased risk of fracture. Certain cancers can affect the way your bones break down and can increase your risk of serious bone problems.

STOBOCLO works by blocking a natural protein in your body called RANKL. This protein signals cells that break down bones. By blocking RANKL, STOBOCLO helps slow bone breakdown, keeping your bones stronger for longer.

STOBOCLO is **not** a cancer treatment.

Why did my doctor prescribe STOBOCLO?

Your doctor prescribed STOBOCLO to help strengthen and protect your bones.

STOBOCLO can be used to strengthen and protect bones at high risk for fracture in:



Men and postmenopausal women with
Osteoporosis



Patients with
Osteoporosis
from long-term steroid treatment



Men with
Bone Loss
from prostate cancer treatment



Women with
Bone Loss
from breast cancer treatment

IMPORTANT SAFETY INFORMATION continued

STOBOCLO can cause serious side effects including:

Increased risk of severe low calcium levels in your blood (hypocalcemia).

STOBOCLO may lower the calcium levels in your blood. Your doctor should treat any low calcium levels before starting STOBOCLO and may prescribe calcium and vitamin D supplements—take these exactly as instructed. If you have advanced chronic kidney disease (with or without dialysis) or chronic kidney disease-mineral

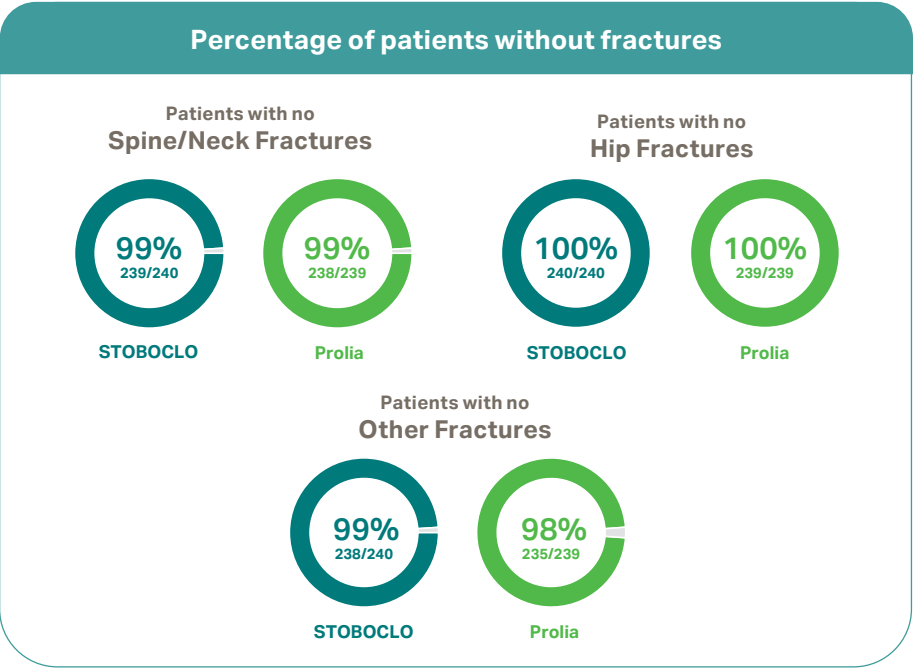
IMPORTANT SAFETY INFORMATION continued

bone disorder (CKD-MBD), your risk of severe hypocalcemia increases, potentially leading to hospitalization, life-threatening events, or death. Your doctor may monitor your blood levels before and during treatment. Low blood calcium often has no symptoms, but call your doctor immediately if you notice muscle spasms, twitches, cramps, or numbness and tingling in your fingers, toes, or around your mouth.

How STOBOCLO can help

STOBOCLO was shown to be as effective and as safe as Prolia®

In a clinical study of 479 postmenopausal women with osteoporosis, both STOBOCLO and Prolia similarly strengthened bones—increasing bone mineral density by about 5%.



Individual results may vary. See the [Medication Guide](#) for full uses for STOBOCLO.

STOBOCLO and Prolia delivered similar results—over 98% of STOBOCLO and Prolia patients did not experience spine/neck, hip, or other fractures.

IMPORTANT SAFETY INFORMATION continued

Serious allergic reactions. Serious allergic reactions have occurred with denosumab products. Call your doctor or seek emergency care immediately if you experience symptoms such as low blood pressure (hypotension), rash, difficulty breathing, itching, throat tightness, hives, or swelling of your face, lips, or tongue.



STOBOCLO is approved to treat other diseases it has not been directly tested on in studies. The FDA looks at a wide variety of tests and data to determine that a drug is biosimilar to another, including clinical trials, blood and immune system evaluations, and chemical analyses. STOBOCLO passed these tests and is officially approved by the FDA as a biosimilar to Prolia.

As the clinical trial continued, these results generally stayed the same.

Of patients who **continued STOBOCLO**:

- 99% had no spine/neck fractures
- 100% had no hip fractures
- 99% had no other fractures

Of patients who **switched to STOBOCLO**:

- 100% had no spine/neck fractures
- 100% had no hip fractures
- 99% had no other fractures

In the same clinical trial of postmenopausal women with osteoporosis, the STOBOCLO safety profile was similar to that of Prolia and was generally well tolerated.

IMPORTANT SAFETY INFORMATION continued

Severe jawbone problems (osteonecrosis). Severe jaw bone problems may happen when you take STOBOCLO. Your doctor should examine your mouth before starting treatment and may advise seeing a dentist. Practice good oral care and consult your doctor or dentist if needed.

Side effects of STOBOCLO

Common side effects of STOBOCLO may include:

In postmenopausal women with osteoporosis:

- Back pain
- Pain in the arms and legs
- High cholesterol levels
- Muscle pain
- Bladder infection

In men with osteoporosis:

- Back pain
- Joint pain
- Common cold (runny nose or sore throat)

In patients with steroid-induced osteoporosis:

- Back pain
- High blood pressure
- Lung infection (bronchitis)
- Headache

In patients receiving certain treatments for prostate or breast cancer:

- Joint pain
- Back pain
- Pain in the arms and legs
- Muscle pain

These are not all the possible side effects of STOBOCLO.

Before starting STOBOCLO, please review the [Medication Guide](#), including “What is the most important information I should know about STOBOCLO?” and ask your physician about the STOBOCLO Risk Evaluation and Mitigation Strategy program, or go to www.stobocloremis.com

Patients with advanced chronic kidney disease, including dialysis-dependent patients, are at risk of severe hypocalcemia (low calcium levels in your blood) following STOBOCLO administration.

Most people with low blood calcium levels do not have symptoms, but some people may have symptoms that include:

- Spasms, twitches, or cramps in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Call your doctor right away if you think you may be having any of these symptoms.



Models are for illustrative purposes only.
Not actual patients.

Call your doctor for medical advice about side effects.
You may report side effects to the FDA at 1-800-FDA-1088.

You may also report side effects to Celltrion USA, Inc.
at 1-800-560-9414.

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STOBOCLO can cause serious side effects including:

Increased risk of severe low calcium levels in your blood (hypocalcemia).

STOBOCLO may lower the calcium levels in your blood. Your doctor should treat any low calcium levels before starting STOBOCLO and may prescribe calcium and vitamin D supplements—take these exactly as instructed. If you have advanced chronic kidney disease (with or without dialysis) or chronic kidney disease-mineral bone disorder (CKD-MBD), your risk of severe hypocalcemia increases, potentially leading to hospitalization, life-threatening events, or death. Your doctor may monitor your blood levels before and during treatment. Low blood calcium often has no symptoms, but call your doctor immediately if you notice muscle spasms, twitches, cramps, or numbness and tingling in your fingers, toes, or around your mouth.

Serious allergic reactions. Serious allergic reactions have occurred with denosumab products. Call your doctor or seek emergency care immediately if you experience symptoms such as low blood pressure (hypotension), rash, difficulty breathing, itching, throat tightness, hives, or swelling of your face, lips, or tongue.

Severe jawbone problems (osteonecrosis). Severe jaw bone problems may happen when you take STOBOCLO. Your doctor should examine your mouth before starting treatment and may advise seeing a dentist. Practice good oral care and consult your doctor or dentist if needed.

Unusual thigh bone fractures. Symptoms include new or unusual pain in your hip, groin, or thigh.

Increased risk of broken bones, including broken bones in the spine, after stopping, skipping or delaying STOBOCLO. Talk with your doctor before starting STOBOCLO treatment. Stopping, skipping, or delaying doses can increase your risk of bone fractures, especially in your spine. This risk is higher if you've already had a spine fracture. Do not change your dosing without consulting your doctor, who may recommend other treatments if STOBOCLO is stopped.

Serious infections. STOBOCLO may increase your risk of serious infections in your skin, abdomen, bladder, ear, or heart (endocarditis). Your risk is higher if you have a weakened immune system or take medicines that affect immunity. You may need hospital treatment if an infection develops. Call your doctor immediately if you experience fever or chills; red, swollen, hot, or tender skin; persistent cough or shortness of breath; severe abdominal pain; or frequent, urgent, or painful urination.

Skin problems. STOBOCLO may cause skin problems like dermatitis, rash, or eczema. Call your doctor if symptoms such as persistent redness, dry or leathery skin, itching, blisters that ooze or crust, small bumps or rash patches, or skin peeling worsen or do not resolve.

Severe bone, joint, or muscle pain. Some people who take denosumab products develop severe bone, joint, or muscle pain.

Do not take STOBOCLO if you have low blood calcium, are pregnant or planning pregnancy, or if you're allergic to denosumab or any ingredients in STOBOCLO.

Before taking STOBOCLO, tell your doctor if you:

- take other denosumab products
- have low blood calcium
- cannot take daily calcium and vitamin D supplements
- have had parathyroid or thyroid surgery
- have malabsorption syndrome (trouble absorbing minerals)
- have kidney problems or receive dialysis
- take medicines that can lower blood calcium
- plan dental surgery or tooth removal
- are pregnant, planning pregnancy, or breastfeeding. STOBOCLO may harm an unborn baby; a pregnancy test is required before treatment; use effective birth control during treatment and for 5 months after your last dose; inform your doctor immediately if pregnancy occurs. It is unknown if STOBOCLO passes into breast milk; do not breastfeed during treatment.

Tell your doctor of all medicines, vitamins, and herbal supplements you take. Keep an updated list to share with healthcare providers.

The most common side effects of STOBOCLO are:

For women with osteoporosis after menopause: back pain, muscle pain, pain in arms and legs, bladder infection, high cholesterol.

For men with osteoporosis: back pain, common cold (runny nose or sore throat), joint pain.

For patients with glucocorticoid-induced osteoporosis: back pain, lung infection (bronchitis), high blood pressure, headache.

For patients treated for prostate or breast cancer: joint pain, pain in arms and legs, back pain, muscle pain.

What to expect during treatment with STOBOCLO

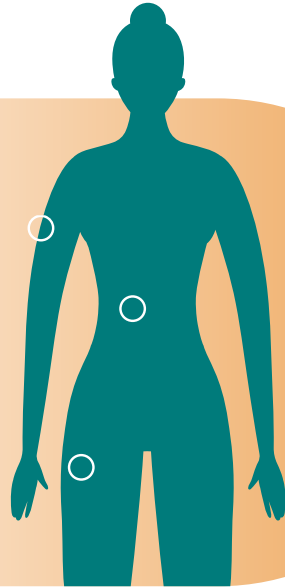
Administration

STOBOCLO is given as a shot under the skin by your healthcare provider. It does not require an infusion.



Your doctor will inject STOBOCLO in one of these 3 locations:

- Upper arm
- Upper thigh
- Stomach area



Your doctor may test your blood calcium level before you start STOBOCLO and while you are taking STOBOCLO.

Kidney function

You can take STOBOCLO even with lower kidney function. If your kidney function is lower than normal, you are at increased risk for low blood calcium levels. Consult your doctor on how best to manage your individual risk.

IMPORTANT SAFETY INFORMATION continued

Unusual thigh bone fractures. Symptoms include new or unusual pain in your hip, groin, or thigh.

Dosing



Your doctor will administer STOBOCLO every 6 months.

- You will receive a 60-mg, single subcutaneous injection
- You may take 1000 mg of calcium and at least 400 IU of vitamin D daily, as directed by your doctor

IMPORTANT SAFETY INFORMATION continued

Increased risk of broken bones, including broken bones in the spine, after stopping, skipping or delaying STOBOCLO. Talk with your doctor before starting STOBOCLO treatment. Stopping, skipping, or delaying doses can increase your risk of bone fractures, especially in your spine. This risk is higher if you've already had a spine fracture. Do not change your dosing without consulting your doctor, who may recommend other treatments if STOBOCLO is stopped.

Starting STOBOCLO

Before you start treatment

Speak to your doctor about your medical history, especially if you are or may become pregnant, or if you have a history of kidney problems.

Your doctor may want to give you some tests to make sure STOBOCLO is right for you. These tests include:



Calcium level test

Your doctor will give you a test to measure the amount of calcium in your blood. If the level is too low, you will probably need to take medicine to bring your calcium level up to normal.



Pregnancy test

If you can become pregnant, your doctor will test to make sure you are not pregnant before starting STOBOCLO. Women should use birth control the entire time they are taking STOBOCLO and for 5 months after their last dose of STOBOCLO.

Make sure you tell your doctor if you are pregnant, are planning to get pregnant, think you may be pregnant, or are breastfeeding.



Dental evaluation

Your doctor will likely want you to have a dental exam before starting STOBOCLO.

Tell your doctor about any tooth pain or dental work you are planning to have. In clinical studies, some people taking denosumab experienced jawbone deterioration, a condition called osteonecrosis of the jaw. Let your dentist know that you are taking STOBOCLO. Make sure you visit your dentist as your doctor recommends.

See the complete
Medication Guide [here](#).

IMPORTANT SAFETY INFORMATION continued

Serious infections. STOBOCLO may increase your risk of serious infections in your skin, abdomen, bladder, ear, or heart (endocarditis). Your risk is higher if you have a weakened immune system or take medicines that affect immunity. You may



IMPORTANT SAFETY INFORMATION continued

need hospital treatment if an infection develops. Call your doctor immediately if you experience fever or chills; red, swollen, hot, or tender skin; persistent cough or shortness of breath; severe abdominal pain; or frequent, urgent, or painful urination.

At your appointment



- Wear loose, comfortable clothing
- Schedule your next appointments in advance as instructed by your doctor

Things to do every day



- Maintain good oral hygiene
 - Brush twice daily
 - Use a fluoride toothpaste
 - Brush for 2 minutes each time you brush
 - Floss your teeth every day
 - Eat a healthy diet and limit sugar
 - Visit your dentist regularly



IMPORTANT SAFETY INFORMATION continued

Skin problems. STOBOCLO may cause skin problems like dermatitis, rash, or eczema. Call your doctor if symptoms such as persistent redness, dry or leathery skin, itching, blisters that ooze or crust, small bumps or rash patches, or skin peeling worsen or do not resolve.

These programs help you get better access to STOBOCLO



Help verify your insurance coverage for STOBOCLO, determine your plan-specific requirements, and understand your available benefits



Connect with Celltrion Cares® for co-pay assistance with your commercial insurance



IMPORTANT SAFETY INFORMATION continued

Severe bone, joint, or muscle pain. Some people who take denosumab products develop severe bone, joint, or muscle pain.



HELP ALONG THE WAY

**Please see Important Safety Information throughout and on pages 8-9.
Full Prescribing Information, including Medication Guide, is available [here](#).**

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