STOBOCLO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using STOBOCLO?

STOBOCLO contains the active ingredient denosumab. STOBOCLO is used to improve bone density and to reduce your risk of fracture. It is used to treat bone loss in women with osteoporosis after menopause, men with osteoporosis, and men with prostate cancer who have reduced testosterone level caused by surgery or treatment with other drugs. It is also used to improve bone density in patients treated with corticosteroids.

For more information, see Section 1. Why am I using STOBOCLO? in the full CMI.

2. What should I know before I use STOBOCLO?

Do not use if you have ever had an allergic reaction to denosumab, medicines produced using Chinese Hamster Ovary cells or any of the ingredients listed at the end of the CMI.

Do not use in patients under 18 years of age.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

Tell your doctor if you have calcium deficiency.

For more information, see Section 2. What should I know before I use STOBOCLO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with STOBOCLO and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use STOBOCLO?

The recommended dose of STOBOCLO is 60 mg given once every 6 months as a single injection under the skin (subcutaneous).

More instructions can be found in Section 4. How do I use STOBOCLO? in the full CMI.

5. What should I know while using STOBOCLO?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using STOBOCLO. • Take calcium and vitamin D supplements if your doctor has told you to. • Maintain good oral hygiene while being treated with STOBOCLO. • Attend all of your treatment and doctor's appointments so that your progress can be checked. • Tell your doctor immediately if you become pregnant while taking STOBOCLO.
Things you should not do	• Do not stop using this medicine without talking to your doctor.
Looking after your medicine	• Store STOBOCLO in the refrigerator (2°C to 8°C) in the original pack to protect from light. • Do not freeze. • Do not shake or vigorously agitate the vial.

For more information, see Section 5. What should I know while using STOBOCLO? in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: signs of an allergic reaction; muscle aches, twitches or cramps; numbness or tingling in your fingers, toes or around your mouth; persistent pain or swelling and/or non-healing sores in your mouth or jaw; pain in your hip, groin, or thigh, which is sometimes severe; severe allergic reaction with skin rash, blisters or fever.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

STOBOCLO®

Active ingredient(s): *denosumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using STOBOCLO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using STOBOCLO.**

Where to find information in this leaflet:

1. Why am I using STOBOCLO?

STOBOCLO contains the active ingredient denosumab. Denosumab is a protein (monoclonal antibody) that attaches (binds) specifically to another unique protein in the body in order to stop the development of bone-removing cells before they reach the bones and cause damage. Treatment with STOBOCLO makes your bone stronger and less likely to break.

STOBOCLO is used to:

- Treat osteoporosis in women after menopause, to reduce the risk of spinal, non-spinal and hip fractures.
- Treat bone loss in men with osteoporosis at increased risk of fracture.
- Treat bone loss that results from a reduction in testosterone level caused by surgery or treatment with drugs in men with prostate cancer.
- Improve bone density in patients treated with corticosteroids.

Bone is a living tissue and is renewed all the time. In women, the ovaries produce the hormone oestrogen which helps keep bones healthy. After menopause, the oestrogen level drops which affects the bone renewal cycle so that more bone is lost than made, resulting in a lower bone mass. This leaves bones thin and fragile.

Osteoporosis is the term used to describe an increased fracture risk, usually with low bone density.

Osteoporosis becomes more common with increasing age. It is more common in women. It can also occur in patients receiving corticosteroids. Many people with osteoporosis have no symptoms but they are still at risk of breaking bones (developing fractures), especially in the spine, hips and wrists.

Other things that can increase the risk of fractures include:

- age
- existence of a previous fracture
- family history of hip fractures
- low body weight
- drinking alcohol
- smoking.

STOBOCLO is prescribed to improve your bone density and to reduce your risk of fracture.

Surgery or medicines used in the treatment of men with prostate cancer to stop the production of testosterone can also lead to bone loss. The bones become weaker and break more easily.

Your doctor, however, may have prescribed STOBOCLO for another reason.

2. What should I know before I use STOBOCLO?

Warnings

Do not use STOBOCLO if:

- you have low calcium levels in your blood (hypocalcaemia). Your doctor may do a blood test to check your calcium levels before you use STOBOCLO.
- you are pregnant, think you may be pregnant, or trying to get pregnant. STOBOCLO may harm your unborn baby.
- you are breast-feeding. It is not known if the active ingredient, denosumab, passes into breast milk.
- you are allergic to denosumab, any medicines that are produced using Chinese Hamster Ovary cells, or any of the ingredients listed at the end of this leaflet. (Always check the ingredients to make sure you can use this medicine)
- you are a child or adolescent. STOBOCLO is not indicated for use in patients under 18 years of age.
- you are taking another medicine containing denosumab.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.
- the solution is cloudy or discoloured. There may be some translucent to white particles of protein in the solution, however the medicine can still be used.

Check with your doctor if you:

- have allergies to any other medicines, or any other substances such as foods, preservatives, or dyes.
- have calcium or vitamin D deficiency. If you are prone to low calcium levels, your doctor will monitor your blood especially in the first few weeks after starting STOBOCLO. Severe low blood calcium levels may lead to hospitalisation, life-threatening events, and death.
- are unable to take daily calcium or vitamin D supplements.

- have or have had severe kidney problems, kidney failure or have needed dialysis, which may increase your chance of getting low blood calcium if you do not take calcium supplements.
- had or have pain in the teeth, gums or jaw, swelling or numbness of the jaw, a "heavy jaw feeling" or loosening of a tooth. A dental condition called jaw osteonecrosis has been rarely reported in patients treated with STOBOCLO. Your doctor should examine your mouth and may ask for a dental examination before you start STOBOCLO. You may need to have dental treatment completed before starting your medicine.
- you may have higher risk of developing jaw problems if you:
  - are undergoing chemotherapy, taking steroids, or are having a dental procedure
  - do not receive routine dental care, have gum disease or have taken STOBOCLO for a long time
- have been told by a doctor or other healthcare professional that you have an intolerance to some sugars.
- take any medicine for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

STOBOCLO has not been tested in pregnant women. Do not use STOBOCLO if you are pregnant, think you may be pregnant, or are trying to get pregnant. STOBOCLO may harm your unborn baby.

Do not use STOBOCLO if you are breast-feeding. It is not known if the active ingredient, denosumab, passes into breast milk. It is important to talk to your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding or whether to stop taking STOBOCLO.

Use in children

Do not use STOBOCLO in children or adolescents under 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking another medicine containing denosumab. If you are taking another medicine containing denosumab, you should not administer STOBOCLO simultaneously.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect STOBOCLO.

4. How do I use STOBOCLO?

How is STOBOCLO given

STOBOCLO is given as an injection under the skin. This is called a subcutaneous injection.

How much STOBOCLO to use

Each dose of STOBOCLO includes 60 mg of the active ingredient denosumab given as a single injection.

When to use STOBOCLO

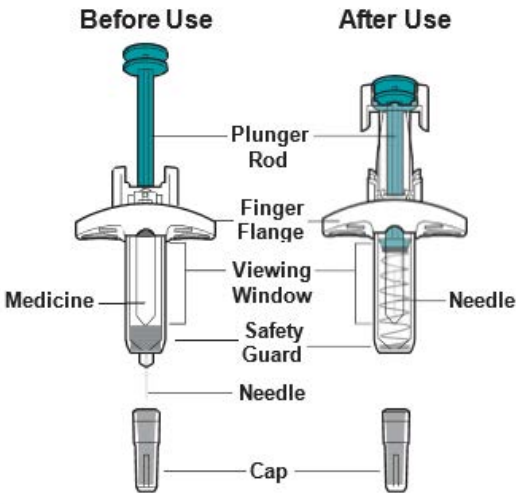
- STOBOCLO is injected once every six (6) months.
- It is important to take your dose of STOBOCLO as scheduled. Do not skip or delay your injection.
- Continue using STOBOCLO for as long as your doctor tells you to. STOBOCLO can treat osteoporosis and bone loss only for as long as you keep having treatment. Please talk to your doctor before you consider stopping treatment.
- You should also take calcium and vitamin D supplements while receiving STOBOCLO. STOBOCLO may lower the calcium levels in your blood. Your doctor, nurse or pharmacist will discuss how much calcium and vitamin D you should take to help prevent low calcium levels.

How to inject STOBOCLO

This section contains information on how you, or the person injecting you (your carer), must use the STOBOCLO pre-filled syringe.

To reduce the risk of accidental injury by the needle, each pre-filled syringe is equipped with an automatic needle guard that is automatically activated to cover the needle after complete delivery of the pre-filled syringe contents.

Guide to parts



Important

Before you or your carer use STOBOCLO pre-filled syringe with automatic needle guard, read this important information:

- It is important that you or your carer do not try to give the injection unless training from a doctor, nurse or pharmacist has been received.
- STOBOCLO is given as an injection into the tissue just under the skin (subcutaneous injection).
- DO NOT remove the needle cap from the pre-filled syringe until you are ready to inject.
- DO NOT use the pre-filled syringe if it has been dropped on a hard surface. Use a new pre-filled syringe and call your doctor, nurse or pharmacist.
- DO NOT attempt to activate the pre-filled syringe prior to injection.
- DO NOT attempt to remove the safety guard from the pre-filled syringe.
- Call your doctor, nurse or pharmacist if you have any questions.

Step 1: Prepare

A: Gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, an adhesive bandage and a sharps disposal container (not included).

For a more comfortable injection, leave the pre-filled syringe at room temperature for about 30 minutes before injecting.

Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the new pre-filled syringe and the other supplies.

- DO NOT try to warm the syringe by using a heat source such as hot water or microwave.
- DO NOT leave the pre-filled syringe exposed to direct sunlight.
- DO NOT shake the pre-filled syringe.

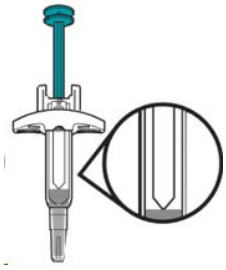
Keep pre-filled syringes out of sight and reach of children.

B: Hold the pre-filled syringe safety guard to remove the pre-filled syringe from the carton.

For safety reasons:

- DO NOT grasp the plunger.
- DO NOT grasp the needle cap.

C: Inspect the medicine and pre-filled syringe



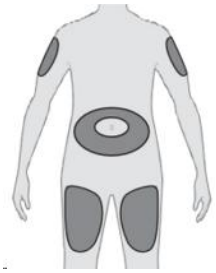
DO NOT use the pre-filled syringe if:

- The medicine is cloudy or there are particles in it. It must be a clear, colourless to slightly yellow solution.
- Any part appears cracked or broken.
- The needle cap is missing or not securely attached.
- The expiry date printed on the label has passed the last day of the month shown.

In all cases, call your doctor, nurse or pharmacist.

Step 2: Get Ready

A: Wash your hands thoroughly. Prepare and clean your injection site.



You can use:

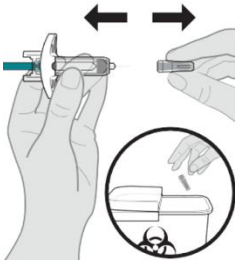
- Upper part of your thigh.
- Belly, except for a 5 cm (2-inch) area right around your belly button.
- Outer area of upper arm (only if someone else is giving you the injection).

Use a different site for each injection.

Clean the injection site with an alcohol wipe. Let the skin dry.

- DO NOT touch or blow the injection site before injecting.
- DO NOT inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

B: Carefully pull the needle cap straight out and away from your body.



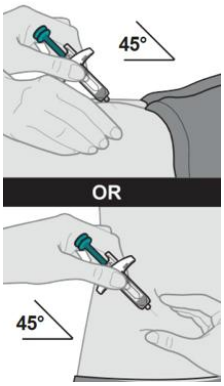
- **DO NOT** hold the plunger rod while removing the cap.
- **DO NOT** re-cap the prefilled syringe.
- **DO NOT** touch the needle.
- You may notice an air bubble in the prefilled syringe or a drop of liquid at the tip of needle. This is normal.

C: Pinch the injection site to create a firm surface.

It is important to keep the skin pinched when injecting.

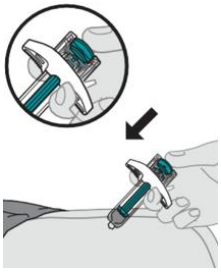
Step 3: Inject

A: Hold the pinch. INSERT the needle into skin.



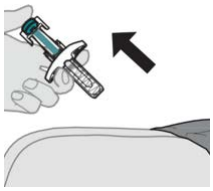
- Hold the body of the pre-filled syringe in one hand between the thumb and index finger.
- Insert the needle into the fold of skin at a 45-degree angle.
- **DO NOT** pull back on the plunger rod at any time.
- After the needle is inserted, release the pinch.

B: PUSH the plunger with slow and constant pressure all the way down.



- **DO NOT** change the position of the prefilled syringe after the injection has started.

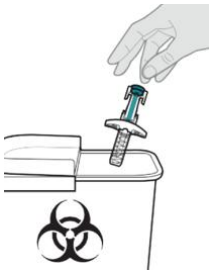
C: RELEASE your thumb. Then LIFT the syringe off the skin.



- After releasing the plunger, the pre-filled syringe safety guard will safely cover the injection needle.

Step 4: Finish

A: Discard the used pre-filled syringe and other supplies in a sharps disposal container.



Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Keep the syringe and sharps disposal container out of sight and reach of children.

- **DO NOT** reuse the pre-filled syringe.
- **DO NOT** recycle pre-filled syringes or throw them into household waste.

B: Examine the injection site

If there is blood, press a cotton ball or gauze pad on your injection site. **DO NOT** rub the injection site. Apply an adhesive bandage if needed.

If you forget to use STOBOCLO

If you miss a dose, STOBOCLO should be administered as soon as possible. From then on, STOBOCLO should be scheduled every 6 months from the date of the last injection.

If you use too much STOBOCLO

If you think that you have used too much STOBOCLO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using STOBOCLO?

Things you should do

- take calcium and vitamin D supplements if your doctor has told you to. Most people do not get enough calcium and vitamin D in their diet and supplements are needed to help strengthen bones.
- practice good dental hygiene while being treated with STOBOCLO.
  Your routine dental hygiene should include brushing your teeth and tongue after every meal, including the evening and gentle flossing once a day to remove plaque.
  Use a mirror and check your teeth and gums regularly for any changes such as sores or bleeding gums. If you notice any problems, tell your doctor and dentist immediately.
- tell any doctor, dentist, nurse, or pharmacist you visit that you are using STOBOCLO.
- if you are about to be started on any other medicine, remind your doctor, nurse or pharmacist that you are being treated with STOBOCLO.
- attend all your doctor's appointments so that your progress can be checked. Your doctor may recommend you to have some tests, X-rays and/or bone density

scans from time to time to make sure the medicine is working.

Call your doctor straight away if you:

- have spasms, twitches, aches or cramps in your muscles, and/or numbness or tingling in your fingers, toes or around your mouth, or have seizures. You may have low levels of calcium in your blood.
- experience any problems with your mouth or teeth such as loose teeth or ill-fitting dentures, pain, or swelling while being treated with STOBOCLO.
- develop a swollen, red area of skin, most commonly in the lower leg, that feels hot and tender (cellulitis) and sometimes experiences fever and chills.
- experience new or unusual pain in your hip, groin, or thigh. Some people have developed unusual fractures in their thigh bone while being treated with STOBOCLO. These fractures may occur with little or no trauma and may involve both thigh bones. This side effect is very rare.
- experience shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin. If you experience any of these side effects, you may be having an allergic reaction to STOBOCLO. These side effects are rare.
- have a severe allergic reaction with skin rash, blisters or fever.
- notice any purple or brownish-red spots, hives, or skin sores. This may be an allergic reaction that can damage blood vessels, mainly in the skin. This side effect is very rare.
- become pregnant while using STOBOCLO. Your doctor can discuss with you the risks of having it while you are pregnant.
  Females that are menstruating should ensure they have adequate contraception while taking STOBOCLO.

Things you should not do

- Do not stop using STOBOCLO without talking to your doctor. After your treatment with STOBOCLO is stopped, or if you skip or delay taking a dose, your risk of breaking bones in your spine is increased, especially if you have a history of broken bones in the spine. If your STOBOCLO treatment is stopped, discuss other available treatment options with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how STOBOCLO affects you.

STOBOCLO has no known effects on the ability to drive or use machines but, as a general precaution, if you are driving soon after an injection, arrange to have someone else drive.

Looking after your medicine

If you need to store STOBOCLO before use, follow the instructions in the carton on how to take care of your medicine properly.

- Store STOBOCLO in the refrigerator between 2°C and 8°C. Do not freeze.
- Keep your medicine in the original carton to protect from light. If you remove the medicine from the carton, it may not keep well.
- Your medicine may be left outside the refrigerator to reach room temperature (up to 30°C) before injection. This will make the injection more comfortable.
- Once your medicine has been left to reach room temperature (up to 30°C), it must be used within 63 days. If you do not use STOBOCLO within the 63 days, you can put it back in the refrigerator for up to 3 days. If it is still not used after this, it must be thrown away.
- Do not keep STOBOCLO at temperatures above 30°C. Warm temperatures will affect how STOBOCLO works.
- Do not shake or vigorously agitate the pre-filled syringe.

Keep it where young children cannot reach it.

When to discard your medicine

STOBOCLO is for single use in one patient only. Dispose of any unused or expired medicine as instructed below.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Muscle and skeleton: • back, muscle or joint pain, or stiffness, most commonly affecting the hips, knees and spine • pain in the arms or legs • aching muscle, muscle tenderness or weakness, not caused by exercise **Skin and hair:** • unusual hair loss or thinning • itchy, red or dry skin **Ears:** • ear pain, discharge from the ear and/or an ear infection. These could be signs of bone damage in the ear **Eyes:** • blurred or cloudy vision	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
General: • high cholesterol levels in the blood	

Serious side effects

Serious side effects	What to do
Signs of an allergic reaction: • shortness of breath • wheezing or difficulty breathing. • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin. • rash that may occur on the skin or sores in the mouth **Signs of low blood calcium (hypocalcaemia):** • muscle spasms, twitches, aches or cramps • numbness or tingling in your fingers, toes or around your mouth. • seizures **Signs of problems with your mouth, teeth or jaw:** • persistent pain or swelling and/or non-healing sores in your mouth or jaw • loose teeth **Signs of bone fractures:** • bone, joint and/or muscle pain, including pain in your hip, groin, or thigh, which is sometimes severe • pain in spine **Signs of skin infection:** • develop a swollen, red area of skin that feels hot and tender (cellulitis) and sometimes experienced with fever and chills • skin rash or blisters with fever **Gut and digestion:** • pain in upper abdomen (belly) that may be accompanied by back pain, nausea, vomiting, fever and/ or sweating **Brain and nerves:** • pain in the extremities, such as hands and feet	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What STOBOCLO contains

Active ingredient (main ingredient)	denosumab
Other ingredients (inactive ingredients)	acetic acid Sodium acetate trihydrate sorbitol polysorbate 20 water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What STOBOCLO looks like

STOBOCLO is a clear, colourless to slightly yellow solution supplied in a pre-filled syringe with an automatic needle guard.

STOBOCLO comes in a single pack size containing 60 mg of denosumab in a volume of 1.0 mL (60 mg/1.0 mL).

Aust R 442991.

The pre-filled syringe with automatic needle guard is not made with natural rubber latex.

Who distributes STOBOCLO

Celltrion Healthcare Australia Pty Ltd

Suite 13.03, 31 Market Street

Sydney 2000, Australia

Phone: 1800 325 228

This leaflet was prepared in April 2026.