Ponlimsi
60 mg Solution for Injection in Pre-filled Syringe
denosumab

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Package leaflet: Information for the user

Ponlimsi®
60 mg Solution for Injection in Pre-filled Syringe
denosumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- Your doctor will give you a patient reminder card, which contains important safety information you need to be aware of before and during your treatment with Ponlimsi.

What is in this leaflet

1. What Ponlimsi is and what it is used for

What Ponlimsi is and how it works
Ponlimsi contains denosumab, a protein (monoclonal antibody) that interferes with the action of another protein, in order to treat bone loss and osteoporosis. Treatment with Ponlimsi makes bone stronger and less likely to break.

Bone is a living tissue and is renewed all the time. Oestrogen helps keep bones healthy. After the menopause, oestrogen level drops which may cause bones to become thin and fragile. This can eventually lead to a condition called osteoporosis. Osteoporosis can also occur in men due to a number of causes including ageing and/or a low level of the male hormone, testosterone. It can also occur in patients receiving glucocorticoids. Many patients with osteoporosis have no symptoms, but they are still at risk of breaking bones, especially in the spine, hips and wrists.

Surgery or medicines that stop the production of oestrogen or testosterone used to treat patients with breast or prostate cancer can also lead to bone loss. The bones become weaker and break more easily.

What Ponlimsi is used for
Ponlimsi is used to treat:
- osteoporosis in women after the menopause (postmenopausal) and men who have an increased risk of fracture (broken bones), reducing the risk of spinal, non-spinal and hip fractures
- bone loss that results from a reduction in hormone (testosterone) level caused by surgery or treatment with medicines in patients with prostate cancer
- bone loss that results from long-term treatment with glucocorticoids in patients who have an increased risk of fracture.

2. What you need to know before you use Ponlimsi

Do not use Ponlimsi if you:
- have low calcium levels in the blood (hypocalcaemia)
- are allergic to denosumab or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Ponlimsi.

Whilst being treated with Ponlimsi you may develop a skin infection with symptoms such as a swollen, red area of skin, most commonly in the lower leg, that feels hot and tender (cellulitis), and possibly with symptoms of fever. Please tell your doctor immediately if you develop any of these symptoms.

You should also take calcium and vitamin D supplements while being on treatment with Ponlimsi. Your doctor will discuss this with you.

You may have low levels of calcium in your blood while receiving Ponlimsi. Please tell your doctor immediately if you notice any of the following symptoms: spasms, twitches, or cramps in your muscle, and/or numbness or tingling in your fingers, toes or around your mouth, and/or seizures, confusion, or loss of consciousness.

Severe low blood calcium levels leading to hospitalisation and even life-threatening reactions have been reported in rare cases. Before each dose and in patients predisposed to hypocalcaemia within two weeks after initial dose, the calcium levels in your blood will therefore be checked (via blood test).

Tell your doctor if you have or have ever had severe kidney problems, kidney failure or have needed dialysis or are taking medicines called glucocorticoids (such as prednisolone or dexamethasone), which may increase your risk of getting low blood calcium if you do not take calcium supplements.

Problems with your mouth, teeth or jaw
A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported rarely (may affect up to 1 in 1,000 people) in patients receiving Ponlimsi for osteoporosis. The risk of ONJ increases in patients treated for a long time (may affect up to 1 in 200 people if treated for 10 years). ONJ can also occur after stopping treatment. It is important to try to prevent ONJ developing as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing ONJ, take the following precautions:
Before receiving treatment, tell your doctor or nurse (health care professional) if you:
- have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction
- do not receive routine dental care or have not had a dental check-up for a long time
- are a smoker (as this may increase the risk of dental problems)
- have previously been treated with a bisphosphonate (used to treat or prevent bone disorders)
- are taking medicines called corticosteroids (such as prednisolone or dexamethasone)
- have cancer.

Your doctor may ask you to undergo a dental examination before you start treatment with Ponlimsi.

While being treated, you should maintain good oral hygiene and receive routine dental check-ups. If you wear dentures you should make sure these fit properly. If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment and tell your dentist that you are being treated with Ponlimsi.

Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of ONJ.

Unusual thigh bone fractures
Some people have developed unusual fractures in their thigh bone while being treated with Ponlimsi. Contact your doctor if you experience new or unusual pain in your hip, groin or thigh.

Children and adolescents
Ponlimsi should not be used in children and adolescents under 18 years of age.

Other medicines and Ponlimsi
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important that you tell your doctor if you are being treated with another medicine containing denosumab.

You should not take Ponlimsi together with another medicine containing denosumab.

Pregnancy and breast-feeding
Ponlimsi has not been tested in pregnant women. It is important to tell your doctor if you are pregnant; think you may be pregnant; or plan to get pregnant. Ponlimsi is not recommended for use if you are pregnant. Women of child-bearing potential should use effective methods of contraception while being treated with Ponlimsi and for at least 5 months after stopping treatment with Ponlimsi.

If you become pregnant during treatment with Ponlimsi or less than 5 months after stopping treatment with Ponlimsi, please inform your doctor.

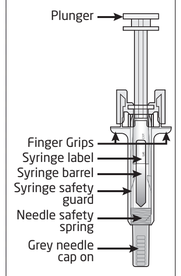
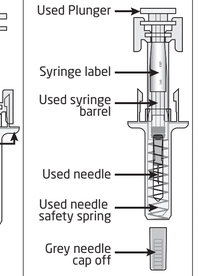
It is not known whether Ponlimsi is excreted in breast milk. It is important to tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding, or whether to stop taking Ponlimsi, considering the benefit of breast-feeding to the baby and the benefit of Ponlimsi to the mother.

If you are breast-feeding during Ponlimsi treatment, please inform your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Instructions for use

Guide to parts

Before use	After use
	

Important

Before you use a Ponlimsi pre-filled syringe with automatic needle guard, read this important information:
- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
- Ponlimsi is given as an injection into the tissue just under the skin (subcutaneous injection).

✗ **Do not** remove the grey 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 or healthcare provider.

✗ **Do not** attempt to activate the pre-filled syringe prior to injection.

✗ **Do not** attempt to remove the clear pre-filled syringe safety guard from the pre-filled syringe.

Call your doctor or healthcare provider if you have any questions.

Step 1: **Prepare**

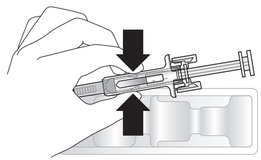
A Remove the pre-filled syringe tray from the package and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, a plaster and a sharps disposal container (not included).

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 the pre-filled syringe out of the sight and reach of children.**

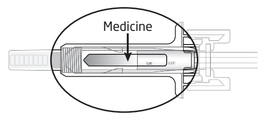
B Open the tray, peeling away the cover. Grab the pre-filled syringe safety guard to remove the pre-filled syringe from the tray.



Grab here

For safety reasons:
✗ **Do not** grasp the plunger.
✗ **Do not** grasp the grey needle cap.

C Inspect the medicine and pre-filled syringe.

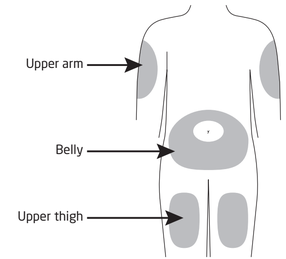


✗ **Do not** use the pre-filled syringe if:
- The medicine is cloudy or there are particles in it. It must be a clear to opalescent, colourless to pale yellow solution.
- Any part appears cracked or broken.
- The grey needle cap is missing or not securely attached.
- The expiry date printed on the label has passed the last day of the month shown.

In all cases, call your doctor or healthcare provider.

Step 2: **Get ready**

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

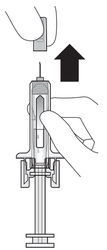


You can use:
- Upper part of your thigh.
- Belly, except for a 5 cm (2-inch) area right around your belly button.
- Outer area of upper arm (only if someone else is giving you the injection).

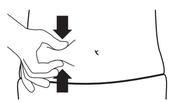
Clean the injection site with an alcohol wipe. Let your skin dry.

✗ **Do not** touch 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 grey needle cap straight out and away from your body.



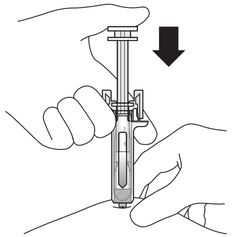
C Pinch your injection site to create a firm surface.



❗ It is important to keep the skin pinched when injecting.

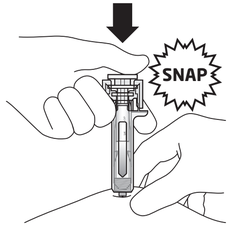
Step 3: **Inject**

A Hold the pinch. INSERT the needle into skin.



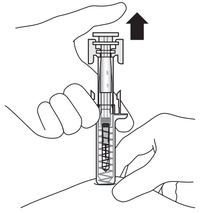
✗ **Do not** touch the cleaned area of the skin.

B PUSH the plunger with slow and constant pressure until you feel or hear a "snap". Push all the way down through the snap.



❗ It is important to push down through the "snap" to deliver your full dose.

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

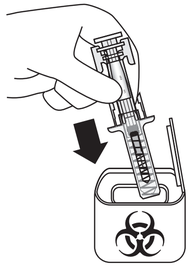


After releasing the plunger, the pre-filled syringe safety guard will safely cover the injection needle.

✗ **Do not** put the grey needle cap back on used pre-filled syringes.

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 a plaster if needed.

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Driving and using machines
Ponlimsi has no or negligible influence on the ability to drive and use machines.

Ponlimsi contains sorbitol
This medicine contains 47 mg sorbitol in each ml of solution.

Ponlimsi contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 60 mg, that is to say essentially 'sodium-free'.

Ponlimsi contains polysorbate 20
This medicine contains 0.1 mg of polysorbate 20 in each syringe which is equivalent to 0.1 mg/ml. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Ponlimsi

The recommended dose is one pre-filled syringe of 60 mg administered once every 6 months, as a single injection under the skin (subcutaneous). The best places to inject are the top of your thighs and the abdomen. Your carer can also use the outer area of your upper arm. Please consult your doctor on the date for a potential next injection.

You should also take calcium and vitamin D supplements while being on treatment with Ponlimsi. Your doctor will discuss this with you.

Your doctor may decide that it is best for you or a carer to inject Ponlimsi. Your doctor or healthcare provider will show you or your carer how to use Ponlimsi. For instructions on how to inject Ponlimsi, please read the section at the end of this leaflet.

Do not shake.

If you forget to use Ponlimsi
If a dose of Ponlimsi is missed, the injection should be administered as soon as possible. Thereafter, injections should be scheduled every 6 months from the date of the last injection.

If you stop using Ponlimsi
To get the most benefit from your treatment in reducing the risk of fractures, it is important to use Ponlimsi for as long as your doctor prescribes it for you. Do not stop your treatment without contacting your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Uncommonly, patients receiving Ponlimsi may develop skin infections (predominantly cellulitis). **Please tell your doctor immediately** if you develop any of these symptoms while being on treatment with Ponlimsi: swollen, red area of skin, most commonly in the lower leg, that feels hot and tender, and possibly with symptoms of fever.

Rarely, patients receiving Ponlimsi may develop pain in the mouth and/or jaw, swelling or non-healing of sores in the mouth or jaw, discharge, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis). **Tell your doctor and dentist immediately** if you experience such symptoms while being treated with Ponlimsi or after stopping treatment.

Rarely, patients receiving Ponlimsi may have low calcium levels in the blood (hypocalcaemia); severely low blood calcium levels may lead to hospitalisation and may even be life-threatening. Symptoms include spasms, twitches, or cramps in your muscles, and/or numbness or tingling in your fingers, toes or around your mouth and/or seizures, confusion, or loss of consciousness. If any of these apply to you, **tell your doctor immediately**. Low calcium in the blood may also lead to a change in heart rhythm called QT prolongation which is seen by electrocardiogram (ECG).

Rarely unusual fractures of the thigh bone may occur in patients receiving Ponlimsi. **Contact your doctor** if you experience new or unusual pain in your hip, groin or thigh as this may be an early indication of a possible fracture of the thigh bone.

Rarely, allergic reactions may occur in patients receiving Ponlimsi. Symptoms include swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin, wheezing or difficulty breathing. **Please tell your doctor** if you develop any of these symptoms while being treated with Ponlimsi.

Very common: may affect more than 1 in 10 people
- bone, joint and/or muscle pain which is sometimes severe
- arm or leg pain (pain in extremity).

Common: may affect up to 1 in 10 people
- painful urination, frequent urination, blood in the urine and inability to hold your urine
- upper respiratory tract infection
- pain, tingling or numbness that moves down your leg (sciatica)
- constipation
- abdominal discomfort
- rash
- skin condition with itching, redness and/or dryness (eczema)
- hair loss (alopecia).

Uncommon: may affect up to 1 in 100 people
- fever, vomiting and abdominal pain or discomfort (diverticulitis)
- ear infection
- rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions).

Very rare: may affect up to 1 in 10,000 people
- allergic reaction that can damage blood vessels mainly in the skin (e.g. purple or brownish-red spots, hives or skin sores) (hypersensitivity vasculitis).

Not known: frequency cannot be estimated from the available data
- talk to your doctor if you have ear pain, discharge from the ear and/or an ear infection. These could be signs of bone damage in the ear.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ponlimsi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C).
Do not freeze.
Keep the pre-filled syringe in the outer carton in order to protect from light.

Your pre-filled syringe 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 syringe has been left to reach room temperature (up to 30°C), do not put it back in the refrigerator and it must be used within 32 days.

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 to protect the environment.

6. Contents of the pack and other information

What Ponlimsi contains
- The active substance is denosumab. Each 1 ml pre-filled syringe contains 60 mg of denosumab (60 mg/ml).
- The other ingredients are sodium acetate trihydrate, acetic acid, glacial, sorbitol (E420), polysorbate 20 and water for injections.

What Ponlimsi looks like and contents of the pack
Ponlimsi is a clear to opalescent, colourless to pale yellow solution for injection provided in a ready to use pre-filled syringe.

Each pack contains one pre-filled syringe with a needle guard.

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer: Merckle GmbH, Graf-Arco-Strasse 3, 89079 Ulm, Germany

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