Package leaflet: Information for the patient

Bilprevda® 120 mg solution for injection
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, pharmacist, or nurse.
- 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, pharmacist or nurse. 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 Bilprevda.

What is in this leaflet

1. What Bilprevda is and what it is used for
2. What you need to know before you use Bilprevda
3. How to use Bilprevda
4. Possible side effects
5. How to store Bilprevda
6. Contents of the pack and other information

1. What Bilprevda is and what it is used for

Bilprevda contains denosumab, a protein (monoclonal antibody) that works to slow down bone destruction caused by cancer spreading to the bone (bone metastasis) or by giant cell tumour of bone.

Bilprevda is used in adults with advanced cancer to prevent serious complications caused by bone metastasis (e.g. fracture, pressure on the spinal cord or the need to receive radiation therapy or surgery).

Bilprevda is also used to treat giant cell tumour of bone, which cannot be treated by surgery or where surgery is not the best option, in adults and adolescents whose bones have stopped growing.

2. What you need to know before you use Bilprevda

Do not use Bilprevda

- if you are allergic to denosumab or any of the other ingredients of this medicine (listed in section 6).

Your healthcare professional will not administer Bilprevda to you if you have a very low level of calcium in your blood which has not been treated.

Your healthcare professional will not administer Bilprevda to you if you have unhealed wounds from dental or oral surgery.

Warnings and precautions

Talk to your doctor before using Bilprevda.

Calcium and vitamin D supplementation
You should take calcium and vitamin D supplements while being treated with Bilprevda unless your blood calcium is high. Your doctor will discuss this with you. If the level of calcium in your blood is low, your doctor may decide to give you calcium supplements before you start treatment with Bilprevda.

Low calcium levels in the blood
Please tell your doctor immediately if you have 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 while being treated with Bilprevda. You may have low levels of calcium in your blood.

Renal impairment
Tell your doctor if you have or have had severe kidney problems, kidney failure or have needed dialysis, which may increase your risk of getting low blood calcium, especially if you do not take calcium supplements.

Problems with your mouth, teeth or jaw
A side effect called osteonecrosis of the jaw (bone damage in the jaw) has been reported commonly (may affect up to 1 in 10 people) in patients receiving denosumab injections for cancer-related conditions. Osteonecrosis of the jaw can also occur after stopping treatment.

It is important to try to prevent osteonecrosis of the jaw developing as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing osteonecrosis of the jaw, there are some precautions you should take:

- Before receiving treatment, tell your doctor/nurse (healthcare professional) if you have any problems with your mouth or teeth. Your doctor should delay the start of your treatment if you have unhealed wounds in your mouth from dental procedures or oral surgery. Your doctor may recommend a dental examination before you start treatment with Bilprevda.
- 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 Bilprevda.
- Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw.

Patients undergoing chemotherapy and/or radiotherapy, taking steroids or anti-angiogenic medicines (used to treat cancer), undergoing dental surgery, who do not receive routine dental care, have gum disease or who are smokers, may have a higher risk of developing osteonecrosis of the jaw.

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

High calcium levels in the blood after stopping treatment with Bilprevda
Some patients with giant cell tumour of the bone have developed high calcium levels in the blood weeks to months after stopping treatment. Your doctor will monitor you for signs and symptoms of high levels of calcium, after you stop receiving Bilprevda.

Children and adolescents

Bilprevda is not recommended for children and adolescents under 18 years of age except for adolescents with giant cell tumour of the bone whose bones have stopped growing. The use of denosumab has not been studied in children and adolescents with other cancers that have spread to bone.

Other medicines and Bilprevda

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription. It is especially important that you tell your doctor if you are being treated with

- another medicine containing denosumab
- a bisphosphonate

You should not take Bilprevda together with other medicines containing denosumab or bisphosphonates.

Pregnancy and breast-feeding

Denosumab 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. Bilprevda is not recommended for use if you are pregnant. Women of child-bearing potential should use effective methods of contraception while being treated with Bilprevda and for at least 5 months after stopping treatment with Bilprevda.

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

It is not known whether denosumab 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 Bilprevda, considering the benefit of breast-feeding to the baby and the benefit of Bilprevda to the mother.

If you are nursing during treatment with Bilprevda, please inform your doctor.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Bilprevda has no or negligible influence on the ability to drive and use machines.

Bilprevda contains sorbitol

This medicine contains 78.2 mg sorbitol in each vial.

Bilprevda contains sorbitol and polysorbate 20

This medicine contains 78.2 mg sorbitol and 0.17 mg polysorbate 20 in each vial. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

Bilprevda contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 120 mg dose, that is to say essentially ‘sodium-free’.

3. How to use Bilprevda

Bilprevda should be administered under the responsibility of a healthcare professional.

The recommended dose of Bilprevda is 120 mg administered once every 4 weeks, as a single injection under the skin (subcutaneous). Bilprevda will be injected into your thigh, abdomen or upper arm. If you are being treated for giant cell tumour of bone, you will receive an additional dose 1 week and 2 weeks after the first dose.

Do not shake.

You should also take calcium and vitamin D supplements while being treated with Bilprevda unless you have an excess of calcium in the blood. Your doctor will discuss this with you.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Please tell your doctor immediately if you develop any of these symptoms while being treated with Bilprevda (may affect more than 1 in 10 people):
- spasms, twitches, cramps in your muscles, numbness or tingling in your fingers, toes or around your mouth and/or seizures, confusion or loss of consciousness. These could be signs that you have low calcium levels in the blood. Low calcium in the blood may also lead to a change in heart rhythm called QT prolongation, which is seen by electrocardiogram (ECG).

Please tell your doctor and dentist immediately if you experience any of these symptoms while being treated with Bilprevda or after stopping treatment (may affect up to 1 in 10 people):
- persistent pain in the mouth and/or jaw, and/or swelling or non-healing of sores in the mouth or jaw, discharge, numbness or feeling of heaviness in the jaw, or loosening of a tooth could be signs of bone damage in the jaw (osteonecrosis).

Very common side effects (may affect more than 1 in 10 people):
- bone, joint, and/or muscle pain which is sometimes severe,
- shortness of breath,
- diarrhoea.

Common side effects (may affect up to 1 in 10 people):
- low phosphate levels in the blood (hypophosphataemia),
- removal of a tooth,
- excessive sweating,
- in patients with advanced cancer: development of another form of cancer.

Uncommon side effects (may affect up to 1 in 100 people):
- high calcium levels in the blood (hypercalcaemia) after stopping treatment in patients with giant cell tumour of the bone,
- new or unusual pain in your hip, groin, or thigh (this may be an early indication of a possible fracture of the thigh bone),
- rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions).

Rare side effects (may affect up to 1 in 1 000 people):
- allergic reactions (e.g. wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching, or hives on the skin). In rare cases, allergic reactions may be severe.

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, pharmacist or nurse. 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 Bilprevda

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 vial in the outer carton in order to protect from light.

The vial may be left outside the refrigerator to reach room temperature (up to 25°C) before injection. This will make the injection more comfortable. Once your vial has been left to reach room temperature (up to 25°C), do not put it back in the refrigerator and it must be used within 30 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 Bilprevda contains

- The active substance is denosumab. Each vial contains 120 mg of denosumab in 1.7 mL solution (corresponding to 70 mg/mL).
- The other ingredients are acetic acid glacial, sodium hydroxide, sorbitol (E420), polysorbate 20 (E432) and water for injections.

What Bilprevda looks like and contents of the pack

Bilprevda is a solution for injection (injection).

Bilprevda is a clear to slightly opalescent, colourless to slightly yellow solution. It may contain trace amounts of clear to white particles.

Each pack contains one single use vial.

Marketing Authorisation Holder and Manufacturer
SciencePharma Sp. z o. o.
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For any information about this medicine, please contact:

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The following information is intended for healthcare professionals only:

- Before administration, the Bilprevda solution should be inspected visually. The solution may contain trace amounts of translucent to white proteinaceous particles. Do not inject the solution if it is cloudy or discolored.
- Do not shake.
- To avoid discomfort at the site of injection, allow the vial to reach room temperature (up to 25ºC) before injecting and inject slowly.
- The entire contents of the vial should be injected.
- A 27 gauge needle is recommended for the administration of denosumab.
- The vial should not be re-entered.

Any unused product or waste material should be disposed of in accordance with local requirements.