B PACKAGE LEAFLET

Package leaflet: Information for the user

Junod 60 mg solution for injection in pre-filled syringe
denosumab

▼This medicinal product 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 card, which contains important safety information you need to be aware of before and during your treatment with Junod.

What is in this leaflet

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

1. What Junod is and what it is used for

What Junod is and how it works

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

Bone is a living tissue and is renewed all the time. Oestrogen helps keep bones healthy.

In women, 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 Junod is used for

Junod is used to treat:
- osteoporosis in women after the menopause (post-menopausal) 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 Junod

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

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

Whilst being treated with denosumab 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 Junod. Your doctor will discuss this with you.

Your blood calcium level may drop during denosumab treatment. 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.

<u>Problems with your mouth, teeth or jaw</u>
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 denosumab 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 the 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 glucocorticoids (such as prednisolone or dexamethasone).
- have cancer.

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

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 Junod.

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 denosumab. Contact your doctor if you experience new or unusual pain in your hip, groin, or thigh.

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

Other medicines and Junod
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 Junod together with another medicine containing denosumab.
Tell your doctor if you are taking medicines called glucocorticoids (such as prednisolone or dexamethasone), see also section „Warnings and precautions".

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

If you become pregnant during treatment with Junod or less than 5 months after stopping treatment with Junod, 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 Junod, considering the benefit of breast-feeding to the baby and the benefit of Junod to the mother.

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

Junod contains sorbitol, polisorbate 20 and sodium
This medicine contains 46 mg sorbitol in each mL of solution.
This medicine contains 0.1 mg of Polysorbate 20 in each 1 mL of solution. Polysorbates may cause allergic reactions. Tell your doctor if you have or your child has any known allergies.
This medicine contains less than 1 mmol sodium (23 mg) per mL that is to say essentially 'sodium-free'.

3. How to use Junod

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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.
Each pack of Junod contains a reminder card, that can be removed from the carton and used to keep a record of the next injection date.

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

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

Do not shake.

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

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

4. Possible side effects

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

Uncommonly (may affect up to 1 in 100 people), patients receiving denosumab may develop skin infections (predominantly cellulitis). **Please tell your doctor immediately** if you develop any of these symptoms while being on treatment with Junod: swollen, red area of skin, most commonly in the lower leg, that feels hot and tender, and possibly with symptoms of fever.

Rarely (may affect up to 1 in 1 000 people), patients receiving denosumab 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 Junod or after stopping treatment.

Rarely (may affect up to 1 in 1 000 people), patients receiving denosumab 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 (may affect up to 1 in 1 000 people), unusual fractures of the thigh bone may occur in patients receiving denosumab. **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 (may affect up to 1 in 1 000 people), allergic reactions may occur in patients receiving

denosumab. 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 Junod.

Very common side effects (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 side effects (may affect up to 1 in 10 people):
- painful urination, frequent urination, blood in the urine, 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 side effects (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 side effects (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 national reporting system listed in Appendix V By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Junod

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.

Do not use this medicine if you notice that the solution contains particles, or it is cloudy or discoloured.

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.

Once removed from the refrigerator, Junod may be stored at room temperature (up to 25 °C) for up to 30 days in the original container and outer packaging in order to protect from light. It must be used within this 30-day period.

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.

6. Contents of the pack and other information

What Junod contains
- The active substance is denosumab. Each 1 mL of pre-filled syringe contains 60 mg denosumab.
- The other ingredients are. acetic acid, glacial; sodium hydroxide; sorbitol (E420); polysorbate 20 (E432) and water for injection.

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

One mL Junod is presented in a single use pre-filled glass syringe (Type I glass) with FluroTec® plunger stopper, staked-in needle (27 G × ½ IN), and rigid needle shield (elastomer + polypropylene rigid shell).

The package contains 1 pre-filled syringe with safety guard.

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Other sources of information

Detailed information on this product is also available by scanning the QR code included below or the outer carton with a smartphone. The same information is also available on the following URL: www.junodinfo.com

QR code to be included

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu, and on the website of {name of Member State Agency (link)}.