A. PACKAGE LEAFLET

Package leaflet: Information for the user

Osqay 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 Osqay.

What is in this leaflet

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

1. What Osqay is and what it is used for

What Osqay is and how it works

Osqay contains denosumab, a protein (monoclonal antibody) that interferes with the action of another protein, in order to treat bone loss and osteoporosis. Treatment with Osqay 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 Osqay is used for

Osqay 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 Osqay

Do not use Osqay

- 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 Osqay.

Whilst being treated with Osqay 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 Osqay. Your doctor will discuss this with you.

You may have low levels of calcium in your blood while receiving Osqay. 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 Osqay 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.
- don’t 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 Osqay.

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 Osqay.

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

Children and adolescents

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

Other medicines and Osqay

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 Osqay together with another medicine containing denosumab.

Pregnancy and breast-feeding

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

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

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

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

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

Driving and using machines

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

Osqay contains sorbitol

This medicine contains 47 mg sorbitol in each mL of solution.

Osqay contains sodium

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

Osqay contains polysorbate
This medicine contains 0.1 mg of polysorbate 20 in each mL of solution. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Osqay

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 Osqay contains a reminder card, that can be removed from the blister insert 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 Osqay. Your doctor will discuss this with you.

Your doctor may decide that it is best for you or a carer to inject Osqay. Your doctor or healthcare provider will show you or your carer how to use Osqay. Read the instructions for use, which is included in the carton on how to use the Osqay pre filled syringe.

Do not shake.

If you forget to use Osqay

If a dose of Osqay 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 Osqay

To get the most benefit from your treatment in reducing the risk of fractures, it is important to use Osqay 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 Osqay may develop skin infections (predominantly cellulitis). **Please tell your doctor immediately** if you develop any of these symptoms while being on treatment with Osqay: 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 Osqay 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 Osqay or after stopping treatment.

Rarely, patients receiving Osqay 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 Osqay. **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 Osqay. 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 Osqay.

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),
- injection site reactions including pain around the site where the injection was given.

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 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 Osqay

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 25°C) before injection. This will make the injection more comfortable. Once your syringe has been left to reach room temperature (up to 25°C), 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 Osqay contains

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

What Osqay looks like and contents of the pack

Osqay is a clear, 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 safety device

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Theramex Ireland Ltd.
3rd Floor Kilmore House
Park Lane Spencer Dock
Dublin 1
D01 YE64
Ireland

Manufacturer
ADOH B.V.
Godfried Bomansstraat 31, Nijmegen,
Gelderland, 6543 JA,
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Instructions for use is enclosed.
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