Package leaflet: Information for the user

Zoledronic acid Seacross 5 mg solution for infusion
zoledronic acid

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.
- 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.

What is in this leaflet

1. What Zoledronic acid Seacross is and what it is used for

Zoledronic acid Seacross contains the active substance zoledronic acid. It belongs to a group of medicines called bisphosphonates and is used to treat post-menopausal women and adult men with osteoporosis or osteoporosis caused by treatment with corticosteroids used to treat inflammation, and Paget's disease of the bone in adults.

Osteoporosis
Osteoporosis is a disease that involves the thinning and weakening of the bones and is common in women after the menopause, but can also occur in men. At the menopause, a woman's ovaries stop producing the female hormone oestrogen, which helps keep bones healthy. Following the menopause bone loss occurs, bones become weaker and break more easily. Osteoporosis could also occur in men and women because of the long term use of steroids, which can affect the strength of bones. Many patients with osteoporosis have no symptoms but they are still at risk of breaking bones because osteoporosis has made their bones weaker. Decreased circulating levels of sex hormones, mainly oestrogens converted from androgens, also play a role in the more gradual bone loss observed in men. In both women and men, Zoledronic acid Seacross strengthens the bone and therefore makes it less likely to break.
Zoledronic acid Seacross is also used in patients who have recently broken their hip in a minor trauma such as a fall and therefore are at risk of subsequent bone breaks.

Paget's disease of the bone
It is normal that old bone is removed and is replaced with new bone material. This process is called remodelling. In Paget's disease, bone remodelling is too rapid and new bone is formed in a disordered fashion, which makes it weaker than normal. If the disease is not treated, bones may become deformed and painful, and may break. Zoledronic acid Seacross works by returning the bone remodelling process to normal, securing formation of normal bone, thus restoring strength to the bone.

2. What you need to know before you use Zoledronic acid Seacross

Follow all instructions given to you by your doctor, pharmacist or nurse carefully before you are given Zoledronic acid Seacross.

Do not use Zoledronic acid Seacross:

- if you are allergic to zoledronic acid, other bisphosphonates or any of the other ingredients of this medicine (listed in section 6).
- if you have hypocalcaemia (this means that the levels of calcium in your blood are too low).
- if you have severe kidney problems.
- if you are pregnant.
- if you are breast-feeding.

Warnings and precautions
Talk to your doctor before you are given Zoledronic acid Seacross:
- if you are being treated with any medicine containing zoledronic acid, which is also the active substance of Zoledronic acid Seacross (zoledronic acid is used in adult patients with certain types of cancer to prevent bone complications or to reduce the amount of calcium).
- if you have a kidney problem, or used to have one.
- if you are unable to take daily calcium supplements.
- if you have had some or all of the parathyroid glands in your neck surgically removed.
- if you have had sections of your intestine removed.

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported in the post-marketing setting in patients receiving zoledronic acid for osteoporosis. ONJ can also occur after stopping treatment.

It is important to try and prevent ONJ developing as it is 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 Zoledronic acid Seacross treatment, tell your doctor, pharmacist or nurse if
- you have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction;
- you do not receive routine dental care or have not had a dental check-up for a long time;
- you are a smoker (as this may increase the risk of dental problems);
- you have previously been treated with a bisphosphonate (used to treat or prevent bone disorders);
- you are taking medicines called corticosteroids (such as prednisolone or dexamethasone);
- you have cancer.

Your doctor may ask you to undergo a dental examination before you start treatment with Zoledronic acid Seacross.

While being treated with Zoledronic acid Seacross, you should maintain good oral hygiene (including regular teeth brushing) and receive routine dental check-ups. If you wear dentures you should make sure these fit properly. If you are under dental treatment or are due to undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment and tell your dentist that you are being treated with Zoledronic acid Seacross. 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 osteonecrosis of the jaw.

Monitoring test
Your doctor should do a blood test to check your kidney function (levels of creatinine) before each dose of Zoledronic acid Seacross. It is important for you to drink at least 2 glasses of fluid (such as water), within a few hours before receiving Zoledronic acid Seacross, as directed by your healthcare provider.

Children and adolescents
Zoledronic acid Seacross is not recommended for anyone under 18 years of age.

Other medicines and Zoledronic acid Seacross

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

It is important for your doctor to know all the medicines you are taking, especially if you are taking any medicines known to be harmful to your kidneys (e.g. aminoglycosides) or diuretics ("waterpills") that may cause dehydration.

Pregnancy and breast-feeding
You must not be given Zoledronic acid Seacross if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Ask your doctor, pharmacist or nurse for advice before taking this medicine.

Driving and using machines
If you feel dizzy while taking Zoledronic acid Seacross, do not drive or use machines until you feel better.

Zoledronic acid Seacross contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per 100 ml vial of Zoledronic acid Seacross, i.e., essentially "sodium free".

3. How to use Zoledronic acid Seacross

Follow carefully all instructions given to you by your doctor or nurse. Check with your doctor or nurse if you are not sure.

Osteoporosis
The usual dose is 5 mg given as one infusion per year into a vein by your doctor or nurse. The infusion will take at least 15 minutes.

In case you recently broke your hip, it is recommended that Zoledronic acid Seacross is administered two or more weeks after your hip repair surgery.

It is important to take calcium and vitamin D supplements (for example tablets) as directed by your doctor.

For osteoporosis, Zoledronic acid Seacross works for one year. Your doctor will let you know when to return for your next dose.

Paget's disease
For the treatment of Paget's disease, Zoledronic acid Seacross should be prescribed only by physicians with experience in the treatment of Paget's disease of the bone.

The usual dose is 5 mg, given to you as one initial infusion into a vein by your doctor or nurse. The infusion will take at least 15 minutes. Zoledronic acid Seacross may work for longer than one year, and your doctor will let you know if you need to be treated again.

Your doctor may advise you to take calcium and vitamin D supplements (e.g. tablets) for at least the first ten days after being given Zoledronic acid Seacross. It is important that you follow this advice carefully so that the level of calcium in your blood does not become too low in the period after the infusion. Your doctor will inform you regarding the symptoms associated with hypocalcaemia.

Zoledronic acid Seacross with food and drink
Make sure you drink enough fluids (at least one or two glasses) before and after the treatment with Zoledronic acid Seacross, as directed by your doctor. This will help to prevent dehydration. You may

eat normally on the day you are treated with Zoledronic acid Seacross. This is especially important in patients who take diuretics ("water pills") and in elderly patients (age 65 years or over).

If you missed a dose of Zoledronic acid Seacross
Contact your doctor or hospital as soon as possible to re-schedule your appointment.

Before stopping Zoledronic acid Seacross therapy
If you are considering stopping Zoledronic acid Seacross treatment, please go to your next appointment and discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Zoledronic acid Seacross.

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.

Side effects related to the first infusion are very common (occurring in more than 30% of patients) but are less common following subsequent infusions. The majority of the side effects, such as fever and chills, pain in the muscles or joints, and headache, occur within the first three days following the dose of zoledronic acid. The symptoms are usually mild to moderate and go away within three days. Your doctor can recommend a mild pain reliever such as ibuprofen or paracetamol to reduce these side effects. The chance of experiencing these side effects decreases with subsequent doses of Zoledronic acid Seacross.

Some side effects could be serious
Common (may affect up to 1 in 10 people)
Irregular heart rhythm (atrial fibrillation) has been seen in patients receiving zoledronic acid for the treatment of postmenopausal osteoporosis. It is currently unclear whether zoledronic acid causes this irregular heart rhythm but you should report it to your doctor if you experience such symptoms after you have received zoledronic acid.

Uncommon (may affect up to 1 in 100 people)
Swelling, redness, pain and itching to the eyes or eye sensitivity to light.

Very rare (may affect up to 1 in 10,000 people)
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.

Not known (frequency cannot be estimated from the available data)
Pain in the mouth and/or jaw, swelling or non-healing 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 zoledronic acid or after stopping treatment.

Kidney disorders (e.g. decreased urine output) may occur. Your doctor should do a blood test to check your kidney function before each dose of zoledronic acid. It is important for you to drink at least 2 glasses of fluid (such as water), within a few hours before receiving zoledronic acid, as directed by your healthcare provider.

If you experience any of the above side effects, you should contact your doctor immediately.

Zoledronic acid may also cause other side effects
Very common (may affect more than 1 in 10 people)
Fever

Common (may affect up to 1 in 10 people)
Headache, dizziness, sickness, vomiting, diarrhoea, pain in the muscles, pain in the bones and/or joints, pain in the back, arms or legs, flu-like symptoms (e.g. tiredness, chills, joint and muscle pain), chills, feeling of tiredness and lack of interest, weakness, pain, feeling unwell, swelling and/or pain at the infusion site.

In patients with Paget's disease, symptoms due to low blood calcium, such as muscle spasms, or numbness, or a tingling sensation especially in the area around the mouth have been reported.

Uncommon (may affect up to 1 in 100 people)
Flu, upper respiratory tract infections, decreased red cell count, loss of appetite, sleeplessness, sleepiness which may include reduced alertness and awareness, tingling sensation or numbness, extreme tiredness, trembling, temporary loss of consciousness, eye infection or irritation or inflammation with pain and redness, spinning sensation, increased blood pressure, flushing, cough, shortness of breath, upset stomach, abdominal pain, constipation, dry mouth, heartburn, skin rash, excessive sweating, itching, skin reddening, neck pain, stiffness in muscles, bones and/or joints, joint swelling, muscle spasms, shoulder pain, pain in your chest muscles and rib cage, joint inflammation, muscular weakness, abnormal kidney test results, abnormal frequent urination, swelling of hands, ankles or feet, thirst, toothache, taste disturbances.

Rare (may affect up to 1 in 1,000 people)
Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone. Low levels of phosphate in the blood.

Not known (frequency cannot be estimated from the available data)
Severe allergic reactions including dizziness and difficulty breathing, swelling mainly of the face and throat, decreased blood pressure, dehydration secondary to acute phase reactions (post-dose symptoms such as fever, vomiting and diarrhoea).

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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zoledronic acid Seacross

Your doctor, pharmacist or nurse knows how to store Zoledronic acid Seacross properly.

- 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 carton and vial after EXP.
- The unopened vial does not require any special storage conditions.
- After opening: Chemical and physical in-use stability has been demonstrated for 24 hours at 2 to 8°C or below 25°C.
- After opening the vial, the product should be used immediately in order to avoid microbial contamination. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C - 8°C. Allow the refrigerated solution to reach room temperature before administration.
- Do not throw away any medicines via wastewater or household water. 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 Zoledronic acid Seacross contains

- The active substance is zoledronic acid. Each vial with 100 ml of solution contains 5 mg zoledronic acid (as monohydrate).
- One ml solution contains 0.05 mg zoledronic acid (as monohydrate).
- The other ingredients are mannitol, sodium citrate and water for injections.

What Zoledronic acid Seacross looks like and contents of the pack

Zoledronic acid Seacross is a clear and colourless solution. 100 ml solution is packed in clear Type II soda lime silica glass vials, capped with Type I chlorobutyl rubber stoppers and sealed with aluminum polypropylene flip off seals.

Zoledronic acid Seacross 5 mg solution for infusion is supplied in:
1 vial

Marketing Authorisation Holder and Manufacturer
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INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for healthcare professionals only (see section 3)

How to prepare and administer Zoledronic acid Seacross

- Zoledronic acid Seacross 5 mg solution for infusion is ready for use.

For single use only. Any unused solution should be discarded. Only clear solution free from particles and discoloration should be used. Zoledronic acid Seacross must not be mixed or given intravenously with any other medicinal product and must be given through a separate vented infusion line at a constant infusion rate. The infusion time must not be less than 15 minutes. Zoledronic acid Seacross must not be allowed to come into contact with any calcium-containing solutions. If refrigerated, allow the refrigerated solution to reach room temperature before administration. Aseptic techniques must be followed during preparation of the infusion. The infusion must be conducted according to standard medical practice.

How to store Zoledronic acid Seacross

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- Do not use this medicine after the expiry date which is stated on the carton and vial after EXP.
- The unopened vial does not require any special storage conditions.
- After opening the vial, the product should be used immediately in order to avoid microbial contamination. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C - 8°C. Allow the refrigerated solution to reach room temperature before administration.