



PATIENT INFORMATION GUIDE

Zoledronic acid Seacross 5mg/100ml solution for infusion

This brochure is intended for patients with an increased risk of bone fractures that are going to be treated with Zoledronic acid Seacross 5mg/100ml solution for infusion (Hereafter refer as Zoledronic acid Seacross 5mg/100ml). Read this brochure carefully because it gives you important information about Zoledronic acid Seacross 5mg/100ml. Please also read the package leaflet of Zoledronic acid Seacross 5mg/100ml for more information.

If you have questions or doubts, talk to your doctor, nurse or pharmacist.

What is Zoledronic acid Seacross 5mg/100ml?

Zoledronic acid Seacross 5mg/100ml is a medicine intended for patients with an increased risk of bone fractures. It belongs to a group of medicines called bisphosphonates: The active ingredient is called zoledronic acid. Zoledronic acid Seacross 5mg/100ml also contains mannitol, sodium citrate and water for injections.

How does Zoledronic acid Seacross 5mg/100ml work?

Zoledronic acid Seacross 5mg/100ml works by binding to the bone and by slowing down bone resorption, which allows the bone forming cells time to rebuild normal bone.

How is Zoledronic acid Seacross 5mg/100ml administered?

The usual dose of Zoledronic acid Seacross 5mg/100ml 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. If you have any questions about the infusion you can talk to your doctor or nurse. It is important to take sufficient calcium through food or combined calcium - and vitamin D supplements. Talk to your doctor about this.

How frequently should I be given a Zoledronic acid Seacross 5mg/100ml infusion?

The usual dose is 1 infusion of Zoledronic acid Seacross 5mg/100ml per year.

What should I tell my doctor before I am given Zoledronic acid Seacross 5mg/100ml?

It is important to tell your doctor the following:

- if you are being treated with other products that contain zoledronic acid, as these products contain the same active substance.
- if you have a history of kidney problems, as your kidneys need to function properly in order to be able to excrete the excess of Zoledronic acid Seacross 5mg/100ml that your

- bones do not need
- if you have had some or all of the parathyroid glands in your neck removed
- if you are unable to take daily calcium supplements
- if you have had sections of your intestine removed
- if you suffer or have suffered from pain, swelling or numbness in your jaw, or from loose or inflamed teeth
- if you use other medicines, including prescribed and over-the-counter medicines, herbal medicines or vitamins

You should not be given Zoledronic acid Seacross 5mg/100ml:

- if you are allergic to Zoledronic acid Seacross 5mg/100ml, to any of its ingredients, or to other bisphosphonates
- if the levels of calcium in your blood are too low
- if you have severe kidney problems
- if you are pregnant, or planning to get pregnant, or if you are breastfeeding

What do I need to do before I am given Zoledronic acid Seacross 5mg/100ml?

Make sure you drink enough fluids (at least two glasses, such as water) before you are given the Zoledronic acid 5 mg infusion. This will help to prevent dehydration. You may eat normally on the day of infusion.

Important side effects of Zoledronic acid Seacross 5mg/100ml

Like all medicines, Zoledronic acid Seacross 5mg/100ml can cause patients to experience side effects.

The majority of the side effects include flu-like symptoms, such as fever and chills, pain in the muscles or joints, and headache. These generally occur within the first three days following the dose of Zoledronic acid Seacross 5mg/100ml. 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 the subsequent dose of Zoledronic acid Seacross 5mg/100ml (in the following year).

If the symptoms described above do not disappear or even get worse, contact your doctor.

Some side effects could be serious

Irregular heart rhythm has been seen in a number of patients receiving Zoledronic acid Seacross 5mg/100ml for post-menopausal osteoporosis. It is currently unclear whether this was caused by Zoledronic acid Seacross 5mg/100ml. If you experience irregular heart rhythm, feel dizzy or are short of breath, you should report this to your doctor.

Pain in the mouth, teeth and jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth, have been observed in patients treated with Zoledronic acid Seacross 5mg/100ml. If you experience these symptoms, talk to your doctor or dentist.

Kidney disorders (e.g. decreased urine output) have been observed in patients receiving Zoledronic acid Seacross 5mg/100ml.

The side effects below are also serious.

A low level of calcium in your blood (hypocalcaemia) may be a side effect of bisphosphonates. Symptoms associated with low blood calcium are muscle spasms, numbness, or a tingling sensation, especially in the area around the mouth. This can be treated taking sufficient calcium through food or combined calcium - and vitamin D supplements. Talk to your doctor about this.

Allergic reactions, including rare cases of difficulty breathing, skin rash, angioedema (swelling of the face, tongue and throat), have been reported in patients treated with Zoledronic acid Seacross 5mg/100ml. Isolated cases of severe allergic reactions have been reported. If you experience any of these symptoms, inform your doctor.

Rare cases of unusual fracture of the thigh bone may occur, particularly in patients on long-term treatment for osteoporosis. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin. These may be early indications of a possible fracture of the thigh bone.

The above description of side effects is not complete. Read the package leaflet, and if you have any further questions on side effects, contact your doctor, pharmacist or nurse. If any of the side effects gets serious, or if you experience side effects that are not described here or in the leaflet, contact your doctor, pharmacist or nurse.

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 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.

Other measures you can take:

- Make sure you exercise regularly (walking or running sports), especially and do (light) weight bearing exercise, to keep your bones strong and your joints supple.
- If you smoke, reduce the amount you smoke or quit smoking altogether. Smoking has a negative effect on the bones.
- Limiting the amount of alcohol you drink may also have a positive effect on the condition of your bones.
- Safe sun exposure also has a beneficial effect on the prevention of osteoporosis.
- Eat a healthy diet and make sure you get enough calcium and vitamin D.