Patient´s information pack:

A Patient's Guide to Aclasta® in osteoporosis

This leaflet is for patients being treated with Aclasta® for osteoporosis with an increased risk of fracture (broken bones).

Please read this leaflet carefully as it gives you important information about Aclasta®.

You should also read the patient information leaflet found in your Aclasta® package.
If you have any questions or are not sure about anything, please ask your doctor, nurse or pharmacist.

Frequently asked questions

What is Aclasta®?

Aclasta® is a medicine for the treatment of patients with osteoporosis who are at increased risk of fracture. It belongs to a group of medicines called bisphosphonates.

The active substance is called zoledronic acid. Aclasta® also contains the following inactive ingredients: mannitol, sodium citrate and water.

How does Aclasta® work?

Aclasta® works by attaching to bone, preventing it from breaking down too much and protecting it from further breakdown. Your doctor can check that Aclasta® is working by carrying out a test called a 'non-invasive bone mineral density assessment'. This test may be a type of X-ray or an ultrasound scan.

How will I receive Aclasta®?

The usual dose of Aclasta® is 5 mg given as an intravenous infusion (drip into a vein). It is given by a doctor or nurse. Each infusion will last at least 15 minutes. If you have any questions regarding the infusion, ask your doctor or nurse.

How often do I need an infusion of Aclasta®?

Aclasta® is given once a year.

Where will I receive Aclasta®?

You may receive treatment at your doctor's office or they may refer you to a special infusion centre. This is part of a hospital where infusions are given for various diseases. Patients do not usually have to stay overnight at these centres.

What should I tell my doctor before I receive Aclasta®?

Before you receive Aclasta® it is important to tell your doctor:

- If you are being treated with any medicine containing zoledronic acid, which is also the active substance of Aclasta®.
- If you have a kidney problem, or used to have one, since your kidneys must be functioning well to remove the excess amount of Aclasta® from your blood.
- If you have had some or all of your parathyroid glands in your neck removed.
- If you have had sections of your intestines removed.
- If you had or have pain, swelling or numbness of the jaw or loosening of the teeth.
- If you are taking any other medicines, including prescription and non-prescription medicines, herbal remedies and vitamins.

You must not receive Aclasta®:

- If you are allergic to Aclasta®, any of its ingredients or any bisphosphonates.
- If your blood calcium levels are too low.
- If you have severe kidney problems.
- If you are pregnant, plan to become pregnant or are breastfeeding.

What should I do before I get my Aclasta®?

It is important to drink plenty of fluids (at least one or two glasses) before your infusion of Aclasta®. This will help to prevent you getting dehydrated.

You may eat normally on the day you are treated with Aclasta®.

What can I expect after my infusion of Aclasta®?

As with all medicines, some people may have side effects when they receive Aclasta®. People taking Aclasta® can experience side effects such as:

- Flu-like symptoms, such as fever and chills.
- Pain in the muscles, bones or joints.
- Headache.

Most of these side effects occur within the first three days following the infusion of Aclasta®. They are usually mild or moderate and tend to go away within three days of the event onset. Your doctor can recommend a mild painkiller such as paracetamol or ibuprofen to manage these side effects. The chance of experiencing these side effects decreases with subsequent doses of Aclasta®. If the symptoms do not go away or get worse, you should speak to your doctor.

Irregular heart rhythm has been seen in patients receiving Aclasta® for post-menopausal osteoporosis. It is currently unclear whether Aclasta® causes this. If you experience palpitations, feel dizzy, or become breathless, tell your doctor.

Pain in the mouth, teeth and jaw, swelling of sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth have been seen in patients treated with Aclasta®. If you experience these symptoms, tell your doctor or dentist.

Low blood calcium level is a possible side effect of bisphosphonates and can be improved by taking enough calcium in the diet or by taking calcium and vitamin D supplements.

Allergic reactions have been reported including rare cases of difficulty breathing, hives and angioedema (such as swollen face, tongue or throat). There have been isolated reports of very serious allergic reactions.

Kidney disorder (e.g. decreased urine output), has been seen in patients receiving Aclasta®.

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.

This is not a complete list of side effects. Read your patient information leaflet, and if you have questions about side effects, you should talk to your doctor. If any of the side effects become serious, or if you notice any side effects not listed in the leaflet, please tell your doctor, pharmacist or nurse.

Will Aclasta® affect my ability to drive?

Adverse reactions, such as dizziness, may affect the ability to drive or use machines, though no studies on this effect with Aclasta have been performed.

Where can I find out more about osteoporosis?

Please ask your doctor or pharmacist for further information.

This leaflet is provided to patients who are being prescribed Aclasta®

Suspected adverse reactions and medication errors associated with the use of Aclasta should be reported to:

Malta Medicines Authority,
Sir Temi Zammit Buildings,
Malta Life Sciences Park,
San Gwann. SGN 3000.

Or at: www.medicinesauthority.gov.mt/adrportal.

Alternatively at: Novartis Pharma Services Inc., Representative Office, Malta by phone on +356 21222872.

Marketing Authorization Holder: Novartis Europharm Limited, Frimley Business Park, Camberley GU16 7SR, United Kingdom.

Local Representative: Novartis Pharma Services Inc., Representative Office Malta.

Tel No.: +356 21222872