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EPAR summary for the public

Ibandronic acid Accord

ibandronic acid

This is a summary of the European public assessment report (EPAR) for Ibandronic acid Accord. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ibandronic acid Accord.

For practical information about using Ibandronic acid Accord, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ibandronic acid Accord and what is it used for?

Ibandronic acid Accord is a medicine used to treat certain conditions affecting bones and blood calcium.

Ibandronic acid Accord solution for injection is used to treat osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and are at risk of developing bone fractures (breaks). Its effect in reducing the risk of spine fractures has been shown in studies, but its effect on the risk of fractures of the neck of the femur (the top of the thighbone) has not been established.

Ibandronic acid Accord concentrate for solution for infusion (drip) is used in adults to:

- prevent 'skeletal events' (fractures or bone complications requiring treatment) in patients with breast cancer and bone metastases (when the cancer has spread to the bone);
- treat hypercalcaemia (high levels of calcium in the blood) caused by tumours.

Ibandronic acid Accord contains the active substance ibandronic acid and is a 'generic medicine'. This means that Ibandronic acid Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU). The reference medicines for Ibandronic acid Accord are Bondronat and Bonviva. For more information on generic medicines, see the question-and-answer document here.

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How is Ibandronic acid Accord used?

Ibandronic acid Accord is available as a solution for injection (3 mg) in a pre-filled syringe and as a concentrate (2 mg and 6 mg) to be made up into a solution for infusion (drip) into a vein. It can only be obtained with a prescription.

For the prevention of skeletal events or the treatment of hypercalcaemia in cancer patients, treatment with this medicine should only be started by a doctor who has experience in the treatment of cancer.

In the prevention of skeletal events in patients with breast cancer and bone metastases, Ibandronic acid Accord is given into a vein as a 6 mg infusion lasting at least 15 minutes every three to four weeks. Patients with moderate or severe kidney problems should receive Ibandronic acid Accord infusions at a lower dose over an hour.

In the treatment of hypercalcaemia caused by tumours, Ibandronic acid Accord is given into a vein as an infusion of 2 or 4 mg, depending on how severe the hypercalcaemia is. The infusion lasts 2 hours. This will normally bring the blood calcium level down to normal levels within a week.

For the treatment of osteoporosis, Ibandronic acid Accord is given as an injection into a vein once every three months. Patients should also take vitamin D and calcium supplements.

How does Ibandronic acid Accord work?

The active substance in Ibandronic acid Accord, ibandronic acid, is a bisphosphonate. It stops the action of osteoclasts, the cells in the body that are involved in breaking down the bone tissue. This reduces bone loss. The reduction of bone loss helps to make bones less likely to break in cancer patients with bone metastases and in women with osteoporosis.

Patients with tumours can have high levels of calcium in their blood, released from the bones. By preventing the breakdown of bones, Ibandronic acid Accord also helps to reduce the amount of calcium released into the blood.

How has Ibandronic acid Accord been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicines, Bondronat and Bonviva, and do not need to be repeated for Ibandronic acid Accord.

As for every medicine, the company provided studies on the quality of Ibandronic acid Accord. There was no need for ‘bioequivalence’ studies to investigate whether Ibandronic acid Accord is absorbed similarly to the reference medicines to produce the same level of the active substance in the blood. This is because Ibandronic acid Accord is given by infusion or injection into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Ibandronic acid Accord?

Because Ibandronic acid Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicines’.

Why is Ibandronic acid Accord approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Ibandronic acid Accord has been shown to be comparable to Bondronat and Bonviva. Therefore, the Agency's view was that, as for Bondronat and Bonviva, the benefit outweighs the identified risk. The Agency recommended that Ibandronic acid Accord be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Ibandronic acid Accord?

The company that markets Ibandronic acid Accord will provide a card to inform patients receiving Ibandronic acid Accord infusion about the risk of osteonecrosis of the jaw and to instruct them to contact their doctor if they get symptoms. Osteonecrosis of the jaw is a condition affecting the bones of the jaw, which could lead to pain, sores in the mouth or loose teeth.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ibandronic acid Accord have also been included in the summary of product characteristics and the package leaflet.

Other information about Ibandronic acid Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Ibandronic acid Accord on 19 November 2012.

The full EPAR for Ibandronic acid Accord can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Ibandronic acid Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicines can also be found on the Agency's website.

This summary was last updated in 08-2017.