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EPAR summary for the public

Iasibon

ibandronic acid

This is a summary of the European public assessment report (EPAR) for Iasibon. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Iasibon.

What is Iasibon?

Iasibon is a medicine that contains the active substance ibandronic acid. It is available as a concentrate that is made up into a solution for infusion (drip into a vein) and as tablets (50 mg).

Iasibon is a 'generic medicine'. This means that Iasibon is similar to a 'reference medicine' already authorised in the European Union (EU) called Bondronat. For more information on generic medicines, see the question-and-answer document here.

What is Iasibon used for?

Iasibon is used in the following ways:

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

The medicine can only be obtained with a prescription.

How is Iasibon used?

Iasibon treatment should only be started by a doctor who has experience in the treatment of cancer.

In the prevention of skeletal events, Iasibon is either given as a 6-mg infusion lasting at least 15 minutes every three to four weeks, or as one tablet once a day. The tablets must always be taken after the patient has not eaten anything for at least six hours overnight and at least 30 minutes before the

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

first food or drink of the day. They must be taken with a full glass of plain water (in areas with hard water, where tap water contains a lot of dissolved calcium, bottled water with a low mineral content should be used). The tablet should be taken while standing or sitting up, and it should not be chewed, sucked or crushed. The patient must not lie down for one hour after taking the tablet. Patients with moderate or severe kidney problems should receive Iasibon infusions at a lower dose over an hour, or the tablets every two days or every week.

In the treatment of hypercalcaemia caused by tumours, Iasibon is given over 2 hours as an infusion of either 2 or 4 mg, depending on how severe the hypercalcaemia is. The infusion will normally bring the blood calcium level down to normal levels within a week.

How does Iasibon work?

The active substance in Iasibon, ibandronic acid, is a bisphosphonate. It stops the action of the osteoclasts, the cells in the body that are involved in breaking down the bone tissue. This leads to less bone loss. The reduction of bone loss helps to make bones less likely to break, which is useful in preventing fractures in cancer patients with bone metastases.

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

How has Iasibon been studied?

Because Iasibon is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Bondronat. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Iasibon?

Because Iasibon is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Iasibon been approved?

The CHMP concluded that, in accordance with EU requirements, Iasibon has been shown to have comparable quality and to be bioequivalent to Bondronat. Therefore, the CHMP's view was that, as for Bondronat, the benefit outweighs the identified risk. The Committee recommended that Iasibon be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Iasibon?

A risk management plan has been developed to ensure that Iasibon is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Iasibon, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Iasibon

The European Commission granted a marketing authorisation valid throughout the European Union for Iasibon on 21 January 2011.

The full EPAR for Iasibon 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 Iasibon, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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

This summary was last updated in 10-2015.