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EPAR summary for the public

Bondronat

ibandronic acid

This is a summary of the European public assessment report (EPAR) for Bondronat. 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 Bondronat.

What is Bondronat?

Bondronat 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).

What is Bondronat used for?

Bondronat is used in adults 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 Bondronat used?

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

In the prevention of skeletal events, Bondronat 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 tablet should be taken after the patient has not eaten anything for at least six hours overnight and at least 30 minutes before the first food or drink of the day. It should be taken with a full glass of plain water (in areas with hard water,

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where tap water contains a lot of dissolved calcium, bottled water with a low mineral content may be used). The patient should not lie down for one hour after taking the tablet. Patients with moderate or severe kidney problems should receive Bondronat infusions at a lower dose over an hour, or the tablet every two days or every week.

In the treatment of hypercalcaemia caused by tumours, Bondronat 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 Bondronat work?

The active substance in Bondronat, 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, Bondronat also helps to reduce the amount of calcium released into the blood.

How has Bondronat been studied?

In the prevention of skeletal events in patients with breast cancer and bone metastases, Bondronat has been compared with placebo (a dummy treatment) in three main studies lasting two years: one with the infusions in 466 patients and two with the tablets in a total of 846 patients. The main measure of effectiveness was based on the number of new bone complications. These included spine fractures, fractures outside the spine and any bone complications that needed treatment with radiotherapy or surgery.

Bondronat has also been studied in the treatment of hypercalcaemia caused by tumours in three four-week studies involving a total of 343 patients. Bondronat was not compared with any other treatments in these studies. The main measure of effectiveness was the change in blood calcium levels.

What benefit has Bondronat shown during the studies?

Bondronat was more effective than placebo in preventing bone complications. It took longer for patients on Bondronat infusions or tablets to develop a new bone complication (50 to 76 weeks) than for patients on placebo (33 to 48 weeks). Bondronat reduced the risk of having a skeletal event by about 40% compared with placebo.

Bondronat was also effective in treating hypercalcaemia caused by tumours. About a half to two-thirds of the patients responded to a 2-mg dose of Bondronat, with blood calcium levels returning to within the normal range. About three-quarters responded to a 4-mg dose.

What is the risk associated with Bondronat?

The most common side effects with Bondronat infusions are a rise in body temperature, hypocalcaemia (low blood calcium levels), asthenia (weakness) and headache. The most common side effects with the tablets are hypocalcaemia and dyspepsia (heartburn). The most serious side effects with Bondronat are anaphylactic reaction (severe allergic reaction), atypical fractures of the femur (an unusual type of

fracture of the bone of the upper leg), osteonecrosis of the jaw (damage to the bones of the jaw, which could lead to pain, sores in the mouth or loosening of teeth), and eye inflammation.

Bondronat must not be used in people with hypocalcaemia. The tablets must not be used in patients who have abnormalities of the oesophagus or who cannot stand or sit up for at least an hour. For the full list of all side effects and restrictions reported with Bondronat, see the package leaflet.

Why has Bondronat been approved?

The CHMP decided that Bondronat's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Bondronat 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 Bondronat, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Bondronat will provide a card to inform patients receiving Bondronat infusion about the risk of osteonecrosis of the jaw and to instruct them to contact their doctor if they experience symptoms.

Other information about Bondronat

The European Commission granted a marketing authorisation valid throughout the European Union for Bondronat on 25 June 1996.

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

This summary was last updated in 04-2016.