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EPAR summary for the public

Bonviva

ibandronic acid

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

What is Bonviva?

Bonviva is a medicine that contains the active substance ibandronic acid. It is available as tablets (150 mg) and as a solution for injection in a prefilled syringe (3 mg).

What is Bonviva used for?

Bonviva 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.

The medicine can only be obtained with a prescription.

How is Bonviva used?

Bonviva can be given either as a tablet or as an injection into a vein. If the tablet is used, the dose is one tablet every month, preferably on the same date each month. The tablet should be taken after an overnight fast, one hour before any food or drink except for water, and 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 may be used.) The patient should not lie down for one hour after taking the tablet. The dose by injection is 3 mg once every three months. Patients taking Bonviva should also take vitamin D and calcium supplements if they do not get enough from their diet.



How does Bonviva work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and more likely to break. Osteoporosis is more common in women after the menopause, when the levels of the female hormone oestrogen fall, since oestrogen helps to keep bones healthy.

The active substance in Bonviva, ibandronic acid, is a bisphosphonate. It stops the action of the osteoclasts, the cells that are involved in breaking down the bone tissue. Blocking the action of these cells leads to less bone loss.

How has Bonviva been studied?

Bonviva has been studied in three main studies involving women with osteoporosis. The first study compared Bonviva 2.5-mg tablets taken once a day with placebo (a dummy treatment) in almost 3,000 women and looked at how many new spine fractures were seen in the patients over three years. The other two studies compared the 150-mg monthly tablets (1,609 patients) and the injections (1,395 patients) with the 2.5-mg once-daily tablets. The studies looked at the change in the density of the bones in the spine and the hip over two years.

The 2.5-mg once-daily tablets used in the studies are no longer authorised.

What benefit has Bonviva shown during the studies?

In the first study, daily treatment with Bonviva 2.5-mg tablets reduced the risk of new spine fractures by 62% in comparison with placebo. The other two studies showed that the 150-mg monthly tablets and the injections were more effective than the 2.5-mg once-daily tablets at increasing bone density in the spine and the hip. Over two years, bone density in the spine increased by 7% with the monthly tablets and by 6% with the injections, compared with 5% with the daily tablets. In the hip, bone density increased by 4% with the monthly tablets and by 3% with the injections, compared with 2% with the daily tablets.

What is the risk associated with Bonviva?

The most common side effects with Bonviva (seen in between 1 and 10 patients in 100) are arthralgia (joint pain) and influenza (flu)-like symptoms. The most serious side effects with Bonviva 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), gastrointestinal (stomach and gut) irritation and eye inflammation. For the full list of all side effects reported with Bonviva, see the package leaflet.

Bonviva must not be used in patients who have hypocalcaemia (low blood calcium levels). The tablets must not be used in patients who have abnormalities of the oesophagus or who cannot stand or sit upright for at least an hour. For the full list of restrictions with Bonviva, see the package leaflet.

Why has Bonviva been approved?

The CHMP decided that Bonviva'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 Bonviva?

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

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

Other information about Bonviva

The European Commission granted a marketing authorisation valid throughout the European Union for Bonviva on 23 February 2004.

The full EPAR for Bonviva can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Bonviva, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2016.