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EPAR summary for the public

Ibandronic Acid Teva

ibandronic acid

This is a summary of the European public assessment report (EPAR) for Ibandronic Acid Teva. 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 Ibandronic Acid Teva.

What is Ibandronic Acid Teva?

Ibandronic Acid Teva is a medicine that contains the active substance ibandronic acid. It is available as tablets (50 and 150 mg).

Ibandronic Acid Teva is a 'generic medicine'. This means that Ibandronic Acid Teva is similar to a 'reference medicine' already authorised in the European Union (EU). The reference medicines for Ibandronic Acid Teva are Bondronat and Bonviva. For more information on generic medicines, see the question-and-answer document [here](#).

What is Ibandronic Acid Teva used for?

Ibandronic Acid Teva 50 mg is used 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).

Ibandronic Acid Teva 150 mg 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. 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 Ibandronic Acid Teva used?

For the prevention of skeletal events, one 50-mg tablet is taken once a day. The tablets must always be taken after the patient has fasted overnight for at least six hours and at least 30 minutes before the first food or drink of the day.

For treating osteoporosis, one 150-mg tablet is taken once a month. The tablet must always be taken after an overnight fast, one hour before any food or drink except for water. Patients should also take vitamin D and calcium supplements if they do not get enough from their diet.

Ibandronic Acid Teva must be taken with a full glass of plain water (but not mineral water) while standing or sitting up, and the tablets should not be chewed, sucked or crushed. The patient must also not lie down for one hour after taking the tablets.

How does Ibandronic Acid Teva work?

The active substance in Ibandronic Acid Teva, 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 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 and in women with osteoporosis.

How has Ibandronic Acid Teva been studied?

Because Ibandronic Acid Teva is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicines. Medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Ibandronic Acid Teva?

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

Why has Ibandronic Acid Teva been approved?

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

Other information about Ibandronic Acid Teva:

The European Commission granted a marketing authorisation valid throughout the EU for Ibandronic Acid Teva on 17 September 2010.

The full EPAR for Ibandronic Acid Teva 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 Teva, 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 06-2015.