

EMA/140299/2015
EMA/H/C/002367

EPAR summary for the public

Ibandronic Acid Sandoz

ibandronic acid

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

What is Ibandronic Acid Sandoz?

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

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

What is Ibandronic Acid Sandoz used for?

Ibandronic Acid Sandoz 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).

The medicine can only be obtained with a prescription.

How is Ibandronic Acid Sandoz used?

The recommended dose is one tablet 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.

Ibandronic Acid Sandoz 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 Sandoz work?

The active substance in Ibandronic Acid Sandoz, 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.

How has Ibandronic Acid Sandoz been studied?

Because Ibandronic Acid Sandoz is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine. 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 Sandoz?

Because Ibandronic Acid Sandoz 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 Ibandronic Acid Sandoz been approved?

The CHMP concluded that, in accordance with EU requirements, Ibandronic Acid Sandoz 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 Ibandronic Acid Sandoz be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Ibandronic Acid Sandoz?

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

Other information about Ibandronic Acid Sandoz:

The European Commission granted a marketing authorisation valid throughout the EU for Ibandronic Acid Sandoz on 26 July 2011.

The full EPAR for Ibandronic Acid Sandoz 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 Sandoz, 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 05-2015.