

BONVIVA[®] FILM-COATED TABLETS

Ibandronic Acid (150mg)

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What Bonviva is used for

Bonviva is a prescription medicine used to treat osteoporosis in women after menopause. Bonviva helps reduce the chance of having fracture (break).

How Bonviva works Bonviva contains the active ingredient ibandronic acid. Bonviva belongs to a group of medicines called bisphosphonates. Bonviva reduces bone loss, with no direct effect on bone formation and increases bone mass.

Before you use Bonviva

- When you must not use it.

You should not take Bonviva if you:

- Are allergic to ibandronic acid or any of the other ingredients of this medicine. (see section **Product description**).
- Are pregnant or breastfeeding.
- Cannot stand or sit upright for at least 60 minutes.
- Have certain problem with your esophagus.
- Have low levels of calcium in your blood.
- Less than 18 years old.

- Before you start to use it

Before you take Bonviva, tell your doctor if you:

- Have problems with swallowing
- Have stomach or digestive problems.
- Have disturbances of bone and mineral metabolism.
- Plan to have dental surgery or teeth removed.
- Have severe kidney problems where creatinine clearance is <30 mL/min.
- Plan to become pregnant or breast-feeding.
- Have cancer
- Have other concomitant therapies, e.g., chemotherapy, radiotherapy, corticosteroid
- Have other diseases e.g., low red blood cell count or hemoglobin, impaired blood clotting, infection, pre-existing dental disease.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including prescription and nonprescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take:

- Antacids for heartburn
- Calcium supplements or other multivalent cations (such as aluminium, magnesium, iron)
- Nonsteroidal antiinflammatory (NSAID) medicines for pain and inflammation.

Other medicines not listed above may also interact with Bonviva. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Bonviva

- How much to use

Take one Bonviva tablet once a month, preferably taken on the same date each month.

- When you use it

Bonviva works only if taken on an empty stomach. Take one Bonviva tablet, after you get up for the day and before taking your first food, drink or other medicine.

- How long to use it

Continue taking Bonviva for as long as your doctor recommends.

- If you forget to use it

If you miss a dose of Bonviva, do not take it later in the day. Take the morning after the tablet is remembered unless the time to the next scheduled dose is within 7 days, you should then return to taking the dose once a month on the originally scheduled date. Call your doctor for instructions.

- If you use too much (overdose)

If you take too much Bonviva, it may result in upper gastrointestinal adverse events, such as upset stomach, heartburn, esophagus or stomach inflammation or ulcer. Owing to the risk of esophageal irritation, do not try to vomit. Do not lie down. Contact your doctor immediately or go to the Emergency Department of your nearest hospital.

While you are using it

- Things you must do

- Take Bonviva while you are sitting or standing.
- Swallow Bonviva tablet with a full glass (180 to 240ml) of plain water only.

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- You should take supplemental calcium or vitamin D if dietary intake is inadequate. - <u>Things you must not do</u> - Do not chew or suck on a tablet of Bonviva. - Do not stop taking Bonviva without first checking with your doctor. - Do not give Bonviva to anyone else, even if they have the same symptoms or condition as you. - <u>Things to be careful of</u> After swallowing Bonviva tablet, wait at least 60 minutes: - Before you lie down. - Before you take your first food or drink except for plain water. Please note that mineral waters should not be used.	You may get allergic reactions, such as hives, breathing difficulties, swelling of your face, lips, tongue or throat, or feeling faint. Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Bonviva. For more information, ask your doctor or pharmacist. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]	and oblong shaped marked 'BNVA' on one side, and '150' on the other side. - <u>Ingredients</u> - Active ingredient Ibandronic Acid monosodium salt monohydrate. - Inactive ingredients <i>Tablet core</i>: Lactose monohydrate, povidone, cellulose microcrystalline, crospovidone, stearic acid, silica colloidal anhydrous <i>Tablet coating</i>: Hypromellose, titanium dioxide, talc (opadry 00A28646), macrogol 6000 - <u>MAL Number</u> MAL21036035ACRZ
Side effects The more common side effects of Bonviva include: - Stomach area (abdominal pain) - Nausea - Gastric inflammation - Diarrhea - Muscle or joint pain - Flu-like symptoms The serious side effects of Bonviva include: - Esophagus problems - Severe jaw bone problems (osteonecrosis)	Storage and Disposal of Bonviva - <u>Storage</u> Keep out of reach and sight of children. Do not store Bonviva above 30°C. - <u>Disposal</u> Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Product Description - <u>What it looks like</u> Bonviva is supplied as tablets that are white to off-white, film-coated	Manufacturer Penn Pharmaceutical Services Ltd, Units 23-24, Tafarnaubach Industrial Estate, Tafarnaubach, Tredegar Gwent NP22 3AA United Kingdom Product Registration Holder -DKSH Malaysia Sdn. Bhd. B-11-01, The Ascent, Paradigm, No. 1 Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia. Date of Revision 04/01/2022 Serial Number NPRA (R2) 20/018