

# BONVIVAÒ

## COMPOSITION:

### (Ibandronate sodium for oral administration)

Each **film-coated tablet** of **BONVIVA** contains:

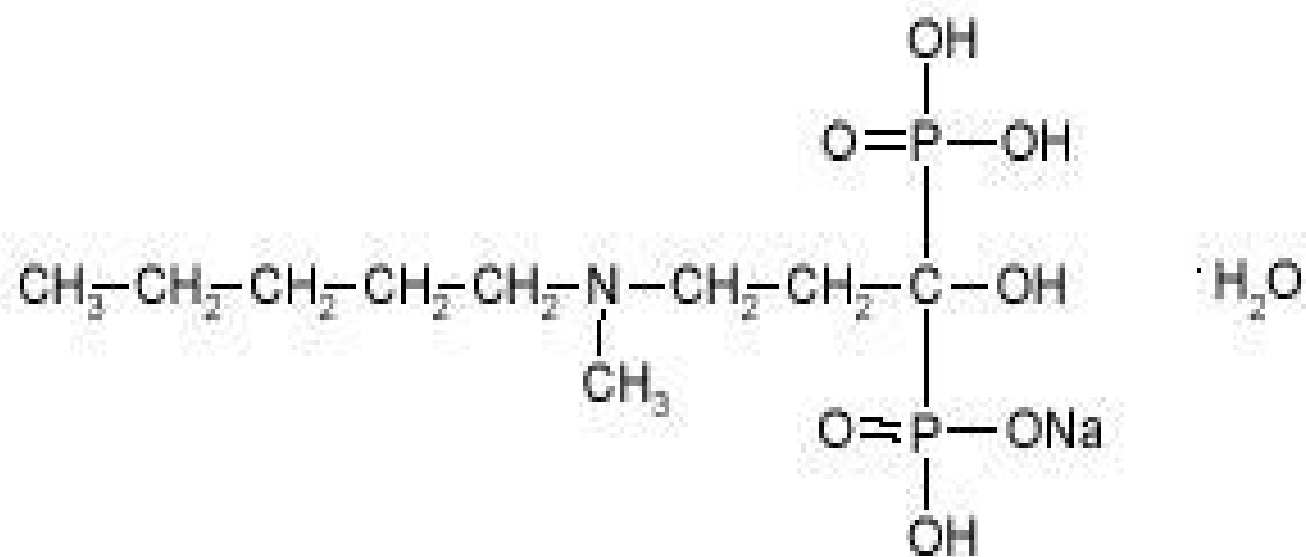
Ibandronate sodium (ibandronic acid)

## DESCRIPTION

:

50 mg

**BONVIVA** (ibandronate sodium) is a nitrogen-containing bisphosphonate that inhibits osteoclast-mediated bone resorption. Ibandronate sodium has the following structural formula:



## Information for Doctors

### HIGHLIGHTS (USPS)

- Original research molecule from Roche
- First, orally administered bisphosphonate that is approved by US FDA for once-monthly dosing schedule
- Proven efficacy in improving the bone strength (BMD) and reducing the risk of vertebral fractures in postmenopausal women.

### CLINICAL PHARMACOLOGY

Bisphosphonates are a preferred class of drugs for managing postmenopausal osteoporosis.

Ibandronate sodium – a 3<sup>rd</sup> generation, nitrogen-containing bisphosphonate - has a great affinity for hydroxyapatite, part of the mineral matrix of bone. Ibandronate inhibits osteoclast activity and reduces bone resorption and turnover. In postmenopausal women, it reduces the elevated rate of bone turnover, leading to a net gain in bone mass.

### INDICATIONS AND USAGE

**BONVIVA** is indicated for the treatment and prevention of osteoporosis in postmenopausal women.

### CONTRAINDICATIONS

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Known hypersensitivity to **BONVIVA** or to any of its excipients

Uncorrected hypocalcemia

Inability to stand or sit upright for at least 60 minutes

### PRECAUTIONS

Use with caution in patients with severe renal impairment ( $Cr_{cl} < 30$  mL/min).

Like other bisphosphonates, **BONVIVA** administered orally may cause upper gastrointestinal disorders such as dysphagia, esophagitis, and esophageal or gastric ulcer.



### *Information for Doctors*

Hypocalcemia and other disturbances of bone and mineral metabolism should be effectively treated before starting **BONVIVA** therapy. Adequate intake of calcium and vitamin D is important in all patients.

## **ADVERSE REACTIONS**

**BONVIVA** is generally well tolerated; adverse events are few, and usually mild and transient. While the incidence of serious adverse events with **BONVIVA** 150 mg once-monthly was 7.1%, the percentage of patients who withdrew from treatment due to adverse events was approximately 7.8%.

Most frequently reported adverse events include nausea, vomiting, diarrhea, constipation, and abdominal pain. Muscular cramps, pains and aches may occur. Headaches, dizziness and skin rashes have been reported. Patients with a previous history of gastrointestinal disease, including those with peptic ulcer without recent bleeding or hospitalization and patients with dyspepsia or reflux controlled by medication, were included in the once-monthly treatment study. For these patients, there was no difference in upper gastrointestinal adverse events with the 150 mg once-monthly regimen compared to 2.5 mg once-daily **BONVIVA** regimen.

## **DOSAGE AND ADMINISTRATION**

Recommended dose of **BONVIVA** for prevention or treatment of postmenopausal osteoporosis is one 150 mg tablet taken once monthly on the same date each month.

To maximize absorption and clinical benefit, **BONVIVA** should be taken at least 60 minutes *before* the *first* food or drink (other than water) of the day, or before taking any oral medication or supplementation, including calcium, antacids, or vitamins. Plain water is the only drink that should be taken with **BONVIVA**. Some mineral waters may contain a higher concentration of calcium, and therefore, should not be used.

To facilitate delivery to the stomach and thus reduce the potential for esophageal irritation, **BONVIVA** tablets should be swallowed whole with a full glass of plain water (6 to 8 oz) while

### *Information for Doctors*

the patient is standing or sitting in an upright position. Patients should *not* lie down for 60 minutes after taking **BONVIVA**.

Do NOT chew or suck the tablet because of a potential for oropharyngeal ulceration.

**BONVIVA 150-mg** tablet should be taken on the same date each month (ie, the patient's **BONVIVA** day). If the once monthly dose is missed, and the patient's next scheduled **BONVIVA** day is more than 7 days away, the patient should be instructed to take one **BONVIVA** 150-mg tablet in the morning following the date that it is remembered. The patient should then return to taking one **BONVIVA 150-mg** tablet every month in the morning of their chosen day, according to their original schedule. However, the patient must not take two 150-mg tablets within the same week. If the patient's next scheduled **BONVIVA** day is only 1 - 7 days away, then the patient must wait until their next scheduled **BONVIVA** day to take their tablet. The patient should then return to taking one **BONVIVA 150-mg** tablet every month in the morning of their chosen day, according to their original schedule.

All patients should receive supplemental calcium or vitamin D if dietary intake is inadequate.

### **PRESENTATION**

**BONVIVA 150 mg** is available in carton of 1 tablet.