

OSTEOMED®
70 mg tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about OSTEOMED

Each tablet of OSTEOMED contains alendronate sodium equivalent to 70 mg of alendronic acid.

Other ingredients are: lactose monohydrate, magnesium stearate

OSTEOMED is a biphosphonate that binds to the bones and specifically inhibits the activity of osteoclasts, the bone-resorbing cells.

OSTEOMED is especially formulated to be taken once weekly.

OSTEOMED is indicated for:

- Treatment of osteoporosis in postmenopausal women
- Prevention of osteoporosis in postmenopausal women
- Treatment of osteoporosis in men

The way to take OSTEOMED

Take OSTEOMED as directed by your physician. Do not discontinue the treatment without consulting your doctor. You must follow the dosing instructions provided by your doctor.

- Swallow the tablet with plenty of water (not less than 200 mL), in an upright position (standing or sitting). Other beverages (such as mineral water, coffee, tea or juice) should be avoided.
- The drug must be taken on an empty stomach, at least 30 minutes before the first food, beverage, or medication of the day.
- This drug should only be taken upon arising for the day. You should not lie down for at least 30 minutes and until after your first food of the day.
- This drug should not be taken at bedtime or before arising for the day.

OSTEOMED is a once weekly medication. Choose the day of the week that best fits your schedule. Every week, take the dose on the same chosen day. The recommended dosage is:

Indication	Dosage
Treatment of osteoporosis in postmenopausal women	One tablet of 70 mg once weekly
Prevention of osteoporosis in postmenopausal women	35 mg (half a tablet of 70 mg) once weekly
Treatment to increase bone mass in men with osteoporosis	One tablet of 70 mg once weekly

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. Milk or antacids should be given to bind alendronate. Due to the risk of esophageal irritation, vomiting should not be induced and the patient should remain fully upright.

In case of missed dose

If you miss a dose, you should take the dose on the morning after you remember. You should not take two tablets on the same day but you should return to taking the dose once a week, as originally scheduled on your chosen day.

Contraindications

This drug is contraindicated in the following cases:

- Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia
- Inability to stand or sit upright for at least 30 minutes
- Hypersensitivity to any component of this product
- Hypocalcemia

Precautions

- You should strictly comply with dosing instructions as provided by your doctor.
- Your doctor may recommend supplemental calcium and vitamin D, if dietary intake is inadequate.
- Inform your doctor if you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn.
- This drug should be used with caution in patients with active upper gastrointestinal problems.
- This drug is not recommended for patients with severe renal insufficiency.
- It is recommended not to administer this drug during pregnancy or lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

It is likely that calcium supplements, antacids, and some oral medications will interfere with the absorption of this drug. Therefore you should wait at least one-half hour after taking this drug before taking any other oral medications.

Caution should be taken during concomitant use with aspirin or non-steroidal anti-inflammatory drugs.

Adverse reactions

This drug is usually well tolerated if the directions for use are followed correctly. The most reported side effects include abdominal pain, nausea, dyspepsia, constipation, diarrhea, flatulence, acid regurgitations, irritation or ulceration of the esophagus, difficulty in swallowing, bone or muscle pain, headache, allergic reactions and black and/or bloody stool.

Inform your doctor if any adverse effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

OSTEOMED, alendronic acid 70 mg (as alendronate sodium), pack of 4 tablets

Revision date: 8/2011

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