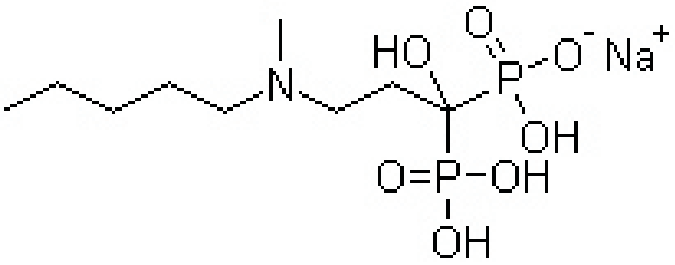
Taj Pharmaceuticals Ltd.

Ibandronate Sodium

CAS No. : 138926-19-9

Molecular Formula C9H22O7NP2Na
Molecular Weight 341.21
CAS Number 138926-19-9



Chemical Name

1 Hydroxy 3(N) Methly 3(N) n
Pentylamino,1,1 Bisphosphonic Acid
Molecular Formula C9H22O7NP2NaH2O
Molecular Weight 359.17

USES

Ibandronate is used to prevent and treat certain types of bone loss (osteoporosis). Osteoporosis causes bones to become thinner and break more easily. Your chance of developing osteoporosis increases after menopause, as you age,Take this medication by mouth usually once a day, or as directed by your doctor. Take this medication after getting up for the day, before taking your first food, beverage or other medication. Do not take it at bedtime or while you are still in bed.

PRECAUTIONS

Before taking ibandronate, tell your doctor or pharmacist if you are allergic to it; or to other bisphosphonates (e.g., alendronate, etidronate, pamidronate, risedronate); or if you have any other allergies.

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have the following conditions: low blood calcium levels (hypocalcemia), inability to sit upright or stand for 60 minutes, severe kidney disease.

MISSED DOSE

If you miss a dose, do not take it later in the day. Take the medication the next morning after you remember. Do not take two tablets on the same day to catch up. Consult your doctor or pharmacist if you have any questions.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children

DOSAGE

Adults

PO 2.5 mg once daily or one 150 mg tablet once monthly on the same date of each month. Take at least 60 min before the first food or drink (other than water) of the day or before taking any oral medication or supplement, including antacids, calcium, or vitamins.

Adults

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IV 3 mg every 3 mo administered over 15 to 30 sec.

General Advice

* Tablets
* Two tablet strengths are available (2.5 mg tablet for once-daily administration and 150 mg tablet for once-monthly administration). Carefully check tablet to ensure proper dose is being administered.
* Do not administer tablets with any liquid other than plain water. Administration of ibandronate tablets with food, medication, juices, mineral water, coffee, or any other beverage will reduce ibandronate absorption and efficacy.

* Injection
* Injection must be administered IV by a health care provider.
* Administer injection using the enclosed needle.
* Prefilled syringes are for single use only; discard unused portion.
* Do not mix injection with calcium-containing solutions or other IV administered drugs.
* If a dose is missed, administer injection as soon as it can be rescheduled. Schedule subsequent injections every 3 mo from the date of last injection and not more frequently than once every 3 mo.
* Patient must receive supplemental calcium and vitamin D.

SIDE EFFECTS

Adverse events associated with the use may include (but are not limited to) the following:

* Dyspepsia
* Diarrhea
* Tooth Disorder
* Vomiting
* Gastritis
* Allergic Reaction
* Infection

Constipation
Influenza-like Illness
Pain in the extremities

PRECAUTIONS

* Ibandronate, like all bisphosphonate medications, can irritate or damage the esophagus and stomach. This can lead to indigestion, heartburn, or even ulcers. Let your healthcare provider know if you notice any of these problems while taking the drug.

* It is important to get enough calcium and vitamin D (either through your diet or by supplementation). Calcium and vitamin D are necessary for rebuilding bone and preventing further bone loss.

* Ibandronate may not be recommended for people with severe kidney disease.

* In rare cases, bisphosphonates (including ibandronate) have caused a condition called osteonecrosis of the jaw. This is a serious, possibly disfiguring, problem in which the bone of the jaw dies. Often, there are symptoms (such as pain, infection, or loosening of the teeth), but sometimes there are no symptoms until a person notices exposed bone.

This problem is most common when bisphosphonates are given by IV (but is still possible when these medications are taken orally). It seems that people who have dental procedures (such as a tooth extraction) are also at higher risk. Be sure to take good care of your mouth and teeth by seeing your dentist frequently. Let your healthcare provider know right away if you think you may have osteonecrosis of the jaw.

* In rare cases, bisphosphonates (including ibandronate) can cause extreme muscle or bone pain. This usually goes away once the medication is stopped.

DRUG DESCRIPTION

Ibandronate Sodium is used in the treatment of metastatic bone disease and elevated serum calcium levels in tumours, Cancer cells, after breaking off from a primary tumour enter the main bloodstream, thereby reaching nearly all tissues of the body. Bones are one of the most common sites for these circulating cells to settle in and start growing. Metastases can occur in bones anywhere in the body, but they are mostly found in bones near the centre of the body.
(ibandronate sodium) is a nitrogen-containing bisphosphonate that inhibits osteoclast-mediated bone resorption. In osteoporosis, where osteoclasts break down bone too quickly, inhibition of this pathway has been shown to slow bone turnover, leading to not only an attenuation of turnover but also a mean increase in bone mass.is specifically indicated for the treatment and prevention of osteoporosis in postmenopausal women

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
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