Taj Pharmaceuticals Ltd.

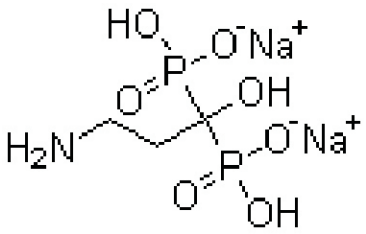
Pamidronate Disodium

CAS No. : 109552-15-0

Synonyms

Disodium 3-amino-1-hydroxy-propylidenebisphosphonate

Molecular Formula C3H9NNa2O7P2
Molecular Weight 279.03
CAS Registry Number 109552-15-0



Pharmacokinetic data

Bioavailability n/a
Protein binding 54%
Metabolism Nil
Half life 28 ± 7 hours
Excretion Renal

DOSAGE

Paget's Disease

Pamidronate Disodium is indicated for the treatment of patients with moderate to severe Paget's disease of bone. The effectiveness of Pamidronate Disodium was demonstrated primarily in patients with serum alkaline phosphatase ≥ 3 times the upper limit of normal. Pamidronate Disodium therapy in patients with Paget's disease has been effective in reducing serum alkaline phosphatase and urinary hydroxyproline levels by ≥ 50% in at least 50% of patients, and by ≥ 30% in at least 80% of patients. Pamidronate Disodium therapy has also been effective in reducing these biochemical markers in patients with Paget's disease who failed to respond, or no longer responded to other treatments. Osteolytic Bone Metastases of Breast Cancer and Osteolytic Lesions of Multiple Myeloma

Pamidronate Disodium is indicated, in conjunction with standard antineoplastic therapy, for the treatment of osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma. The Pamidronate Disodium treatment effect appeared to be smaller in the study of breast cancer patients receiving hormonal therapy than in the study of those receiving chemotherapy, however, overall evidence of clinical benefit has been demonstrated.

Paget Disease
Adults

IV 30 mg/day as a 4-h infusion on 3 consecutive days for a total dose of 90 mg. For retreatment, same as initial therapy, when clinically indicated.

Osteolytic Bone Metastases of Breast Cancer

Adults

IV 90 mg as a 2-h infusion every 3 to 4 wk.
Osteolytic Bone Lesions of Multiple Myeloma
Adults

IV 90 mg as a 4-h infusion on a monthly basis. General Advice

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Pamidronate
Disodium
CAS NO- 109552-15-0

* For IV administration only. Not for intradermal, subcutaneous, IM, intra-arterial, or oral administration.
* Concentrated injection solution must be further diluted before administration.
* Reconstitute lyophilized powder with 10 mL sterile water for injection. Allow drug to dissolve completely before withdrawing for further dilution.
* Do not administer if particulate matter or discoloration noted.
* Administer diluted solution via separate IV line.

Hypercalcemia of malignancy

* Dilute the recommended dose in 1,000 mL 0.45% or sodium chloride 0.9% or dextrose 5% injection. Infuse prescribed dose over 2 to 24 h as ordered.

Paget disease

* Dilute the recommended dose in 500 mL 0.45% or sodium chloride 0.9% or dextrose 5% injection. Infuse prescribed dose over 4 h.

Osteolytic bone lesions of multiple myeloma

* Dilute the recommended dose in 500 mL 0.45% or sodium chloride 0.9% or dextrose 5% injection. Infuse prescribed dose over 4 h.

SIDE EFFECTS

Mild fever, redness/swelling/pain at the injection site, stomach pain, loss of appetite, dizziness, headache, nausea, vomiting, or constipation may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.
A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching, swelling, severe dizziness, trouble breathing.

PRECAUTIONS

Osteonecrosis of the jaw (ONJ) has been reported predominantly in cancer patients treated with intravenous bisphosphonates, including . Many of these patients were also receiving chemotherapy and corticosteroids which may be risk factors for ONJ. Postmarketing experience and the literature suggest a greater frequency of reports of ONJ based on tumor type (advanced breast cancer, multiple myeloma), and dental status (dental extraction, periodontal disease, local trauma including poorly fitting dentures). Many reports of ONJ involved patients with signs of local infection including osteomyelitis.

Cancer patients should maintain good oral hygiene and should have a dental examination with preventive dentistry prior to treatment with bisphosphonates.
While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition.

For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Nursing Mothers

It is not known whether is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when is administered to a nursing woman.

Pediatric Use

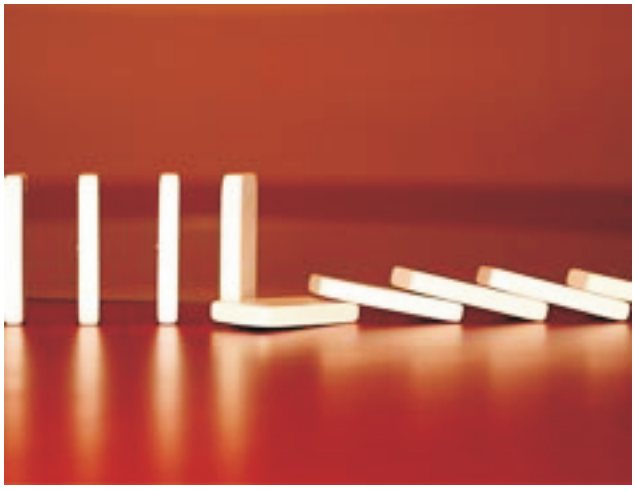
Safety and effectiveness of in pediatric patients have not been established.

DRUG DESCRIPTION

Pamidronate disodium is a white-to-practically-white powder. It is soluble in water and in 2N sodium hydroxide, sparingly soluble in 0.1N hydrochloric acid and in 0.1N acetic acid, and practically insoluble in organic solvents.Inactive Ingredients. Mannitol, USP, and phosphoric acid (for adjustment to pH 6.5 prior to lyophilization).

Distribution
Adsorbed to bone in areas of high turnover.
Metabolism

Not metabolized.
Elimination



Treatment of moderate to severe hypercalcemia associated with malignancy with or without bone metastases; treatment of moderate to severe Paget disease of bone; treatment of osteolytic bone lesions of multiple myeloma and bone metastases of breast cancer in conjunction with standard chemotherapy.
Unlabeled Uses

Treatment of postmenopausal osteoporosis; treatment of hyperparathyroidism; prevention of glucocorticoid-induced osteoporosis; management of immobilization-related hypercalcemia; reduction of bone pain in prostatic carcinoma.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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