Taj Pharmaceuticals Ltd.

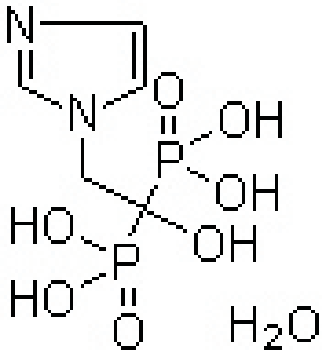
Zoledronic Acid

CAS No. : 165800-06-6

Systematic (IUPAC) name

(1-hydroxy-2-imidazol-1-yl-1-phosphono-ethyl)phosphonic acid

Molecular Formula C5H10N2O7P2.H2O
Molecular Weight 290.10
CAS Registry Number 165800-06-6



Chemical data

Formula C5H10N2O7P2
Mol. mass 272.09 g/mol

Pharmacokinetic data

Bioavailability ?
Protein binding 22%
Metabolism Nil
Half life 146 hours
Excretion Renal (partial)

DOSAGE

Follow all instructions for proper mixing and dilution with the correct IV fluids. Do not mix this drug with calcium-containing mixing solutions (e.g., Lactated Ringers). If you have questions regarding the use of this medication, consult your pharmacist. Give this medication by vein (IV) over at least 15 minutes in a saline (0.9% sodium chloride) or dextrose (D5W) solution as directed by your doctor. Additional IV fluids may be given before, during, or after your treatment with this drug. The dosage is based on your medical condition and response to therapy but should not be greater than 4 mg (each dose) or be given faster than the recommended rate (over 15 minutes). Doses greater than 4 mg or given quickly increase the risk for kidney problems. Consult your doctor or pharmacist. It may take up to 7 days before the full benefit of this drug takes effect. Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid. Learn how to store and discard needles and medical supplies safely.

Zoledronic acid comes as a solution (liquid) to inject into a vein over at least 15 minutes. It is usually injected by a health care provider in a doctor's office, hospital, or clinic. When zoledronic acid injection is used to treat high blood levels of calcium caused by cancer it is usually given as a single dose. A second dose may be given at least 7 days after the first dose if blood calcium does not drop to normal levels or does not remain at normal levels. When zoledronic acid injection is used to treat bone damage caused by multiple myeloma or cancer that has spread to the bones, it is usually given once every 3-4 weeks. When zoledronic acid injection is used to treat osteoporosis, it is usually given once a year. When zoledronic acid is used to treat Paget's disease of bone, it is usually given as as a single dose, but additional doses may be given after some time has passed. You may experience a reaction during the first few days after you receive a dose of zoledronic acid injection. Symptoms of this reaction may include flu-like symptoms, fever, headache, and bone or muscle pain. These symptoms may begin during the first 3 days after you receive a dose of zoledronic acid injection and may last 3-14 days. Your doctor may recommend that you take a nonprescription pain reliever/fever reducer after you receive zoledronic acid injection to prevent or treat these symptoms.

Taj Pharmaceuticals Ltd.
Zoledronic Acid
CAS NO- 165800-06-6

SIDE EFFECTS

Zoledronic acid may cause side effects.
* redness or swelling in the place where you received your injection
* red, swollen, or teary eyes
* constipation
* nausea
* vomiting
* diarrhea
* stomach pain
* loss of appetite
* weight loss
* heartburn
* mouth sores
* excessive worry
* agitation
* depression
* difficulty falling asleep or staying asleep
* fever, chills, and other signs of infection
* white patches in the mouth
* swelling, redness, irritation, burning, or itching of the vagina
* white vaginal discharge
* numbness, burning, or tingling in fingers or toes
* hair loss

Some side effects can be serious.
* rash
* hives
* itching
* swelling of the eyes, face, lips, tongue, throat, hands, arms, feet, ankles, or lower legs
* difficulty breathing or swallowing
* upper chest pain
* irregular heartbeat
* numbness or tingling around the mouth
* sudden tightening of muscles
* unusual bruising or bleeding
* painful or swollen gums
* loosening of the teeth
* numbness or heavy feeling in the jaw
* poor healing of the jaw

PRECAUTIONS

Before receiving zoledronic acid injection,
* tell your doctor and pharmacist if you are allergic to zoledronic acid or any other medications.* tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: aminoglycoside antibiotics such as amikacin , gentamicin , kanamycin , neomycin , paromomycin , streptomycin, and tobramycin ; cancer chemotherapy medications; loop diuretics ('water pills') such as bumetanide , ethacrynic acid , and furosemide ; oral steroids such as dexamethasone methylprednisolone , and prednisone and thalidomide . Many other medications may interact with zoledronic acid, so tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

* tell your doctor if you have ever had a low level of calcium in your blood. Your doctor will probably check the level of calcium in your blood before you begin treatment and may not prescribe this medication if the level is too low.
* tell your doctor if you have been treated with zoledronic acid or other bisphosphonates in the past; if you have ever had surgery on your parathyroid gland (small gland in the neck) or thyroid gland or surgery to remove sections of your small intestine; and if you have or have ever had heart failure (condition in which the heart cannot pump enough blood to other parts of the body); anemia (condition in which red blood cells cannot bring enough oxygen to other parts of the body); any condition that stops your blood from clotting normally; any condition that prevents your body from absorbing nutrients from food or problems with your mouth, teeth, or gums; an infection, especially in your mouth; asthma, especially if it is made worse by aspirin; or parathyroid, kidney, or liver disease.
* tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. You should use a reliable method of birth control to prevent pregnancy while you are receiving zoledronic acid. If you become pregnant while receiving zoledronic acid, call your doctor. Talk to your doctor if you plan to become pregnant at any time in the future because zoledronic acid may remain in your body for years after you stop receiving it.

DRUG DESCRIPTION

Zoledronic acid is in a group of medicines called bisphosphonates (bis FOS fo nayts). Zoledronic acid inhibits the release of calcium from bones.Zoledronic acid is used to treat Paget's disease, and high blood levels of calcium caused by cancer (hypercalcemia of malignancy). Zoledronic acid also treats multiple myeloma (a type of bone marrow cancer) or bone cancer that has spread from elsewhere in the body. Zoledronic acid is also used to treat osteoporosis in postmenopausal women.

Zoledronic acid is a white crystalline powder. Its molecular formula is C5H10N2O7P2•H2O and its molar mass is 290.1g/Mol. Zoledronic acid is highly soluble in 0.1N sodium hydroxide solution, sparingly soluble in water and 0.1N hydrochloric acid, and practically insoluble in organic solvents. The pH of a 0.7% solution of zoledronic acid in water is approximately 2.0.

Zoledronic acid is used to treat a condition of the bones (hypercalcemia of malignancy-HCM) sometimes caused by cancer. This condition causes high calcium levels (hypercalcemia) and weakens your bones.

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:
91 022 30601000.
This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).
MPSTJ278
Last revised: 29 August 2009