



Pamidronate Injection

(pa mi droe' nate)

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IMPORTANT WARNING:

[Posted 11/12/2008] FDA issued an update to the Agency's review of safety data regarding the potential increased risk of atrial fibrillation in patients treated with a bisphosphonate drug. Bisphosphonates are a class of drugs used primarily to increase bone mass and reduce the risk for fracture in patients with osteoporosis, slow bone turnover in patients with Paget's disease of the bone, and to treat bone metastases and lower elevated levels of blood calcium in patients with cancer. FDA reviewed data on 19,687 bisphosphonate-treated patients and 18,358 placebo-treated patients who were followed for 6 months to 3 years. The occurrence of atrial fibrillation was rare within each study, with most studies containing 2 or fewer events. Across all studies, no clear association between overall bisphosphonate exposure and the rate of serious or non-serious atrial fibrillation was observed. Additionally, increasing dose or duration of bisphosphonate therapy was not associated with an increase rate of atrial fibrillation. Healthcare professionals should not alter their prescribing patterns for bisphosphonates and patients should not stop taking their bisphosphonate medication. For more information visit the FDA website at: <http://www.fda.gov/Safety/MedWatch>, and <http://www.fda.gov/Drugs>.

Why is this medication prescribed?

Pamidronate is used to treat high levels of calcium in the blood that may be caused by certain types of cancer. Pamidronate is also used along with cancer chemotherapy to treat bone damage caused by multiple myeloma (cancer that begins in the plasma cells [a type of white blood cell that produces substances needed to fight infection]) or by breast cancer that has spread to the bones. Pamidronate is also used to treat Paget's disease (a condition in which the bones are soft and weak and may be deformed, painful, or easily broken). Pamidronate injection is in a class of medications called bisphosphonates. It works by slowing bone breakdown, increasing bone density (thickness) and decreasing the amount of calcium released from the bones into the blood.

How should this medicine be used?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Pamidronate injection comes as a solution (liquid) to inject into a vein slowly, over 2-24 hours. It is usually injected by a health care provider in a doctor's office, hospital, or clinic. It may be given once every 3-4 weeks, once a day for 3 days in a row, or as a single dose that may be repeated after 1 week or longer. The treatment schedule depends on your condition.

Your doctor may recommend a calcium supplement and a multivitamin containing vitamin D to take during your treatment. You should take these supplements every day as directed by your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Before receiving pamidronate injection,

- tell your doctor and pharmacist if you are allergic to pamidronate injection, alendronate (Fosamax), etidronate (Didronel), risedronate (Actonel), tiludronate (Skelid), zoledronic acid (Zometa), any other medications, or any of the ingredients in pamidronate injection. Ask your pharmacist for a list of the ingredients.
- 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: cancer chemotherapy medications; oral steroids such as dexamethasone (Decadron, Dexone), methylprednisolone (Medrol), and prednisone (Deltasone); and thalidomide (Thalomid). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with pamidronate injection, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you are being treated with radiation therapy and if you have or have ever had thyroid surgery, seizures, or liver or kidney 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 pamidronate. If you become pregnant while receiving pamidronate, call your doctor immediately. Talk to your doctor if you plan to become pregnant at any time in the future because pamidronate may remain in your body for years after you stop using it.
- you should know that pamidronate may cause serious problems with your jaw, especially if you have dental surgery or treatment while you are taking the medication. A dentist should examine your teeth and perform any needed treatments before you start to receive pamidronate. Be sure to brush your teeth and clean your mouth properly while you are receiving pamidronate. Talk to your doctor before having any dental treatments while you are receiving this medication.
- you should know that pamidronate injection may cause severe bone, muscle, or joint pain. You may begin to feel this pain within days, months, or years after you first receive pamidronate injection. Although this type of pain may begin after you have received pamidronate injection for some time, it is important for you and your doctor to realize that it may be caused by pamidronate. Call your doctor right away if you experience severe pain at any time during your treatment with pamidronate injection. Your doctor may stop giving you pamidronate injection and your pain may go away after you stop treatment with this medication.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet

What should I do if I forget a dose?

Call your doctor if you miss a dose of pamidronate or an appointment to receive a dose of pamidronate.

What side effects can this medication cause?

Pamidronate injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- redness, swelling, or pain in the injection spot
- stomach pain
- loss of appetite
- constipation
- nausea
- vomiting
- heartburn
- change in ability to taste food
- sores in the mouth
- fever
- headache
- dizziness
- excessive tiredness
- difficulty falling asleep or staying asleep
- coughing
- difficulty urinating or painful urination
- swelling of the hands, arms, feet, ankles, or lower legs

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:

- painful or swollen gums
- loosening of the teeth
- numbness or heavy feeling in the jaw
- poor healing of the jaw
- vomit that is bloody or looks like coffee grounds
- bloody or black and tarry stools
- shortness of breath
- fast heartbeat
- fainting
- sudden tightening of muscles
- numbness or tingling around the mouth
- eye pain or tearing

Pamidronate injection may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/Safety/MedWatch>] or by phone [1-800-332-1088].

What storage conditions are needed for this medicine?

If you are administering this medication at home, your health care provider will tell you how to store it. Follow these instructions carefully.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- fever
- change in ability to taste food
- sudden tightening of the muscles
- numbness or tingling around the mouth

What other information should I know?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to pamidronate injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Aredia®

Other names

- ADP Sodium
- AHPPrBP Sodium

Last Revised - 05/01/2008