



Zoledronic Acid Injection

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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/SafetyInformation>, and <http://www.fda.gov/Drugs/DrugSafety>.

Why is this medication prescribed?

Zoledronic acid (Reclast) is used to treat osteoporosis (condition in which the bones become thin and weak and break easily) in women who have undergone menopause ('change of life,' end of regular menstrual periods). Zoledronic acid (Reclast) is also used to treat Paget's disease of bone (a condition in which the bones are soft and weak and may be deformed, painful, or easily broken). Zoledronic acid (Zometa) is used to treat high levels of calcium in the blood that may be caused by certain types of cancer. Zoledronic acid (Zometa) is also used along with cancer chemotherapy to treat bone damage caused by multiple myeloma [cancer that begins in the plasma cells (white blood cells that produce substances needed to fight infection)] or by cancer that began in another part of the body but has spread to the bones. Zoledronic acid (Zometa) is not cancer chemotherapy, and it will not slow or stop the spread of cancer. However, it can be used to treat bone disease in patients who have cancer. Zoledronic acid 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.

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 a single dose, but additional doses may be given after some time has passed.

Your doctor may prescribe or 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. Tell your doctor if there is any reason that you will not be able to take these supplements during your treatment.

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.

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 zoledronic acid injection,

- tell your doctor and pharmacist if you are allergic to zoledronic acid or any other medications.
- you should know that zoledronic acid injection is available under the brand names Zometa and Reclast. You should only be treated with one of these products at a time.
- 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 (Amikin), gentamicin (Garamycin), kanamycin (Kantrex), neomycin (Neo-Rx, Neo-Fradin), paromomycin (Humatin), streptomycin, and tobramycin (Tobi, Nebcin); cancer chemotherapy medications; loop diuretics ('water pills') such as bumetanide (Bumex), ethacrynic acid (Edecrin), and furosemide (Lasix); oral steroids such as dexamethasone (Decadron, Dexone), methylprednisolone (Medrol), and prednisone (Deltasone); and thalidomide (Thalomid). 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.
- you should know that zoledronic acid 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 zoledronic acid injection. Although this type of pain may begin after you have received zoledronic acid injection for some time, it is important for you and your doctor to realize that it may be caused by zoledronic acid. Call your doctor right away if you experience severe pain at any time during your treatment with zoledronic acid injection. Your doctor may stop giving you zoledronic acid injection and your pain may go away after you stop treatment with this medication.
- you should know that zoledronic acid may cause serious problems with your jaws, especially if you have dental surgery or treatment while you are using the medication. A dentist should examine your teeth and perform any needed treatments before you start to use zoledronic acid. Be sure to brush your teeth and clean your mouth properly while you are using zoledronic acid. Talk to your doctor before having any dental treatments while you are using this medication.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet. Eat and drink normally on the day(s) you receive a dose of zoledronic acid. Be sure to drink at least 2 glasses of water or another liquid within a few hours before you receive zoledronic acid.

What should I do if I forget a dose?

If you miss an appointment to receive a zoledronic acid infusion, call your doctor as soon as possible.

What side effects can this medication cause?

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.

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

- 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. If you experience any of the following symptoms, call your doctor immediately:

- 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

Zoledronic acid 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?

Your doctor will store this medication in his or her office and give it to you as needed.

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
- weakness
- muscle cramps
- fast, pounding, or irregular heartbeat
- dizziness
- depression
- difficulty walking
- seizures
- confusion
- shortness of breath

- sudden tightening of muscles
- numbness, burning, or tingling in fingers or toes
- muscle weakness
- double vision
- difficulty speaking

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 zoledronic acid.

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

- Reclast®
- Zometa®

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