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Zoledronic Acid Injection

pronounced as (zoe' le dron ik)

Why is this medication prescribed?

Zoledronic acid (Reclast) is used to prevent or 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 osteoporosis in men, and to prevent or treat osteoporosis in men and women who are taking glucocorticoids (a type of corticosteroid medication that may cause osteoporosis). 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?

Zoledronic acid comes as a solution (liquid) to inject into a vein over at least 15 minutes. It is usually injected by a healthcare 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 to 4 weeks. When zoledronic acid injection is used to treat osteoporosis in women who have undergone menopause, or in men, or to treat or prevent osteoporosis in people who are taking glucocorticoids, it is usually given once a year. When zoledronic acid is used to prevent osteoporosis in women who have undergone menopause, it is usually given once every 2 years. 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.

Be sure to drink at least 2 glasses of water or another liquid within a few hours before you receive zoledronic acid.

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, chills, and bone, joint 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 to 14 days. Your doctor may tell you to take a nonprescription pain reliever/fever reducer after you receive zoledronic acid injection to prevent or treat these symptoms.

If you are receiving zoledronic acid injection to prevent or treat osteoporosis, you must continue to receive the medication as scheduled even if you are feeling well. You should talk to your doctor from time to time about whether you still need to be treated with this medication.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with zoledronic acid injection and each time you receive a dose. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website} to obtain the Medication Guide.

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?

Before receiving zoledronic acid injection,

- tell your doctor and pharmacist if you are allergic to zoledronic acid or any other medications, or any of the ingredients in zoledronic acid injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- 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); aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn); cancer chemotherapy medications; digoxin (Lanoxin, in Digitek); diuretics ('water pills') such as bumetanide (Bumex), ethacrynic acid (Edecrin), and furosemide (Lasix); and oral steroids such as dexamethasone (Decadron, Dexone), methylprednisolone (Medrol), and prednisone (Deltasone). 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 or have ever had kidney disease or if you have a dry mouth, dark urine, decreased sweating, dry skin, and other signs of dehydration or recently have had diarrhea, vomiting, fever, infection, excessive sweating, or have been unable to drink enough fluids. Your doctor will wait until you are no longer dehydrated before giving you zoledronic acid injection or if you have certain types of kidney disease may not prescribe this treatment for you. Also 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 (Actonel, Actonel+Ca, Aredia, Boniva, Didronel, Fosamax, Fosamax+D, Reclast, Skelid, and Zometa) 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; low levels of calcium, magnesium, or potassium in your blood; 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 or wheezing, especially if it is made worse by taking aspirin; or parathyroid 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. Zoledronic acid may harm the fetus. 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 or months 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 osteonecrosis of the jaw (ONJ, a serious condition of the jaw bone), 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, including cleaning, 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.

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?

Zoledronic acid may cause side effects. Tell your doctor if any of these symptoms, or those listed in the HOW or PRECAUTIONS sections, are severe or do not go away:

- itching, redness, pain, or swelling in the place where you received your injection
- red, swollen, itchy, or teary eyes or swelling around the 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, cough, and other signs of infection
- white patches in the mouth
- swelling, redness, irritation, burning, or itching of the vagina
- white vaginal discharge
- numbness or tingling around the mouth or 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
- hoarseness
- difficulty breathing or swallowing

- upper chest pain
- irregular heart beat
- muscle spasms, twitches, or cramps
- unusual bruising or bleeding
- painful or swollen gums
- loosening of the teeth
- numbness or heavy feeling in the jaw
- sore in the mouth or the jaw that does not heal

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

Being treated with a bisphosphonate medication such as zoledronic acid injection for osteoporosis may increase the risk that you will break your thigh bone(s). You may feel dull, aching pain in your hips, groin, or thighs for several weeks or months before the bone(s) break, and you may find that one or both of your thigh bones have broken even though you have not fallen or experienced other trauma. It is unusual for the thigh bone to break in healthy people, but people who have osteoporosis may break this bone even if they do not receive zoledronic acid injection. Talk to your doctor about the risks of receiving zoledronic acid injection.

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 (<http://www.fda.gov/Safety/MedWatch> [http://www.fda.gov/Safety/MedWatch]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

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 the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [https://www.poisonhelp.org/help]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- fever
- weakness
- sudden tightening of muscles or muscle cramps
- fast, pounding, or irregular heart beat

- dizziness
- uncontrollable eye movements
- double vision
- depression
- difficulty walking
- uncontrollable shaking of a part of your body
- seizures
- confusion
- shortness of breath
- pain, burning, numbness or tingling in the hands or feet
- difficulty speaking
- difficulty swallowing
- decreased urination

What other information should I know?

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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