

17.2 FDA-Approved Patient Labeling

Reclast® (pronounced RE-klast) (zoledronic acid) Injection

IMPORTANT: You should not receive Reclast if you are already receiving Zometa. Reclast and Zometa are the same medicine. They both contain zoledronic acid.

Read this leaflet carefully before your first infusion of Reclast and before each infusion. There may be new information. This leaflet does not replace talking with your healthcare professional.

What is the most important information I should know about Reclast?

Patients with severe kidney problems should not receive Reclast Injection.

Low blood calcium should be corrected prior to receiving Reclast. If you are being treated for Paget's disease of the bone it is important to take 1500 mg of calcium and 800 IU of vitamin D daily, especially during the first 2 weeks after getting Reclast. You should take calcium and vitamin D daily as recommended by your healthcare professional.

What is Reclast?

Reclast is a prescription medicine used to:

- Treat osteoporosis in women after menopause, and in patients after a recent hip fracture
- Prevent osteoporosis in women after menopause
- Increase bone mass in men with osteoporosis
- Treat and prevent osteoporosis in men and women caused by treatment with steroid medicines such as prednisone
- Treat men and women with Paget's disease of the bone

Reclast strengthens your bones by increasing bone mass and lowers the chance of breaking bones (fractures).

Who should not get Reclast?

You should not get Reclast if:

- Your blood calcium level is too low.
- You are allergic to zoledronic acid or any other ingredient in Reclast. See section 'What are the ingredients in Reclast' for a complete list of ingredients.

Talk to your healthcare provider before taking this medication if you have any of these conditions.

What should I tell my doctor before getting Reclast?

Reclast may not be right for you. Tell your doctor about all your medical conditions, including if you:

- have kidney problems
- have or have had low blood calcium
- are not able to take daily calcium and vitamin D supplements
- had parathyroid or thyroid surgery (these glands are located in your neck)
- have trouble absorbing minerals in your stomach or intestines ("malabsorption syndrome")
- had sections of your intestine removed
- have asthma (wheezing) from taking aspirin
- have a planned dental surgery such as tooth extraction
- are pregnant or plan to become pregnant; Reclast may harm your unborn baby
- are breast-feeding or planning to breast-feed. It is not known if Reclast passes into breast milk.
- have recent vomiting, diarrhea or decreased appetite

Tell your doctor about all the medicines you take, including prescription and nonprescription drugs, vitamins and minerals, and herbal supplements. Some medicines may increase your chance for low blood calcium levels or kidney problems when used with Reclast. **Especially tell your doctor if you are taking:**

- Zometa
- A diuretic or "water pill"
- Non-steroidal anti-inflammatory medicines (NSAIDS).
- An antibiotic. Certain antibiotics called aminoglycosides may increase the effect of Reclast in lowering your blood calcium for a long period of time.

Ask your healthcare provider or pharmacist to learn if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist each time you get a new medicine.

How will I receive Reclast?

- Reclast is always given to you by a healthcare provider. Reclast is given by infusion into a vein (IV) that should take at least 15 minutes .
- Before you receive Reclast, drink at least 2 glasses of fluid (such as water) within a few hours as directed by your healthcare provider. You may eat normally before your infusion.

For Osteoporosis:

- To treat osteoporosis Reclast is given once a year
- To prevent osteoporosis Reclast is given once every 2 years

- In patients with osteoporosis, the current recommended daily intake of calcium is 1200 mg and vitamin D 800 IU to 1000 IU daily. If you have osteoporosis you should take calcium and vitamin D daily as recommended by your doctor.
- During treatment with Reclast, your doctor may order a bone mineral density test to check your osteoporosis.

For Paget's Disease:

- Is given as a single treatment or your doctor may choose to give you more Reclast infusions based on signs or symptoms of your disease.
- To prevent low blood calcium, it is important to take calcium and vitamin D supplements. If you have Paget's disease you should take 1500 mg of calcium a day in divided doses (for example, 750 mg two times a day, or 500 mg three times a day) and 800 IU vitamin D a day. It is especially important to take the calcium and vitamin D supplements during the first 2 weeks after getting Reclast.
- During treatment with Reclast, your doctor may order a blood test to check your Paget's disease.

What are the possible side effects of Reclast?

Reclast may cause serious side effects. Call your healthcare provider right away if you have any of these symptoms after receiving Reclast:

- **Low blood calcium (hypocalcemia).** Symptoms may include numbness or tingling feeling (especially in the area around the mouth) or muscle spasms. Call your doctor right away if you notice any of these symptoms after receiving Reclast.
- **Kidney problems.** Your doctor may do a blood test to check your kidneys before each dose of Reclast. It is important for you to drink at least 2 glasses of fluid (such as water), within a few hours before receiving Reclast, as directed by your healthcare provider.
- **Jaw-bone problems (Osteonecrosis of the jaw).** Jaw-bone problems may occur in some people and include: infection, slower healing after teeth are pulled.
- **Severe muscle, bone and joint pain.** Tell your doctor if you have severe muscle, bone, or joint pain after receiving Reclast.

The most common side effects of Reclast include: flu-like illness, fever, pain in your muscles or joints, and headache that can happen over several days after you get Reclast. Ask your healthcare provider how to lessen these symptoms. Acetaminophen (a mild pain reliever) may reduce these symptoms. The side effects lessen each time you receive Reclast.

Tell your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of Reclast. If you have questions, talk to your healthcare provider.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General Information about Reclast

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets.

This leaflet is a summary of the most important information about Reclast. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Reclast that is written for healthcare professionals. For more information, go to www.reclast.com or call 1-866-732-5278.

What are the ingredients in Reclast?

Active ingredient: zoledronic acid. **Inactive ingredients:** mannitol, USP; sodium citrate, USP; and water for injection, USP.

What is Osteoporosis?

Osteoporosis is a disease that involves a thinning and weakening of bones. Weaker bone can break more easily. Throughout life your body keeps your bones strong and healthy by replacing old bone with new bone. In osteoporosis, however, the body removes bone faster than it is formed. This causes loss of bone mass and weakening of bones. Weak bones are more likely to break. Osteoporosis is common in women after menopause, with increasing age, and may also occur in men. People who have an increased risk of osteoporosis: 1) are Caucasian (white) or Asian; 2) are thin; 3) have a family member with osteoporosis; 4) do not get enough calcium or vitamin D; 5) do not exercise; 6) smoke or drink alcohol often or 7) take medicines that cause bone loss (like prednisone – a steroid) over a period of time.

At first, osteoporosis usually has no symptoms, but people with osteoporosis are more likely to break (fracture) their bones. Fractures most often occur at the hip, back (spine), or wrist bones. Fractures of the spine may not be painful, but over time they can make you shorter. Over time fractures can lead to pain, severe disability, or loss of ability to move around. Reclast strengthens your bones and therefore makes them less likely to break.

What is Paget's disease of bone?

Normally bone breaks down and is replaced by new bone. In Paget's disease, bone breaks down too much and the new bone made is not normal. Bones affected by Paget's disease like the skull, spine, and legs, become deformed and weaker than normal. This can cause problems like bone pain and the bones can bend or break.

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