

Handling

After opening the solution, it is stable for 24 hours at 2°C – 8 °C (36°F - 46°F).

If refrigerated, allow the refrigerated solution to reach room temperature before administration.

Storage

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (17.2).

17.1 Information for Patients

Patients should be made aware that Reclast contains the same active ingredient (zoledronic acid) found in Zometa®, and that patients being treated with Zometa should not be treated with Reclast.

Before being given Reclast patients should tell their doctor if they have kidney problems and what medications they are taking.

Reclast should not be given if the patient is pregnant or plans to become pregnant, or if she is breast-feeding [see *Contraindications* (4)].

If the patient had surgery to remove some or all of the parathyroid glands in their neck, or had sections of their intestine removed, or are unable to take calcium supplements they should tell their doctor.

Reclast is given as an infusion into a vein by a nurse or a doctor, and the infusion time must not be less than 15 minutes.

On the day of treatment the patient should eat and drink normally, which includes drinking at least 2 glasses of fluid such as water within a few hours prior to the infusion, as directed by their doctor, before receiving Reclast.

After getting Reclast it is strongly recommended patients with Paget's disease take calcium in divided doses (for example, 2 to 4 times a day) for a total of 1500 mg calcium a day to prevent low blood calcium levels. This is especially important for the two weeks after getting Reclast [see *Warnings and Precautions* (5.2)].

Adequate calcium and vitamin D intake is important in women with osteoporosis and the current recommended daily intake of calcium is 1200 mg and vitamin D 400IU – 800IU daily. All patients should be instructed on the importance of calcium and vitamin D supplementation in maintaining serum calcium levels.

Patients should be aware of the most commonly associated side effects of therapy. Patients may experience one or more side effects that could include: fever, flu-like symptoms, myalgia, arthralgia, and headache. Most of these side effects occur within the first 3 days following the dose of Reclast. They usually resolve within 3 days of onset but may last for up to 7 to 14 days. Patients should consult their physician if they have questions or if these symptoms persist. The incidence of these symptoms decreased markedly with subsequent doses of Reclast. Administration of acetaminophen or ibuprofen following Reclast administration may reduce the incidence of these symptoms.

Physicians should inform their patients there have been reports, primarily in patients treated with bisphosphonates for other illnesses, of persistent pain and/or a non-healing sore of the mouth or jaw, and if they experience these symptoms to tell their physician or dentist.

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 the Patient information carefully before your first infusion of Reclast and before each infusion. There may be new information. This leaflet does not replace talking with your doctor.

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 health care professional.

What is Reclast?

Reclast is a medicine used to treat:

- Osteoporosis in women after menopause
- 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 anything in Reclast. See section 'What are the ingredients in Reclast' for a complete list of ingredients

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 a history of 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 a 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

Tell your doctor about all the medicines you take, including prescription and nonprescription drugs, herbal supplements, and vitamins. **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"
- An antibiotic. Certain antibiotics called aminoglycosides may increase the effect of Reclast in lowering your blood calcium for a long period of time.

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

How will I receive Reclast?

- Reclast is given by infusion into a vein (IV) that takes at least 15 minutes time. Reclast is always infused by your doctor or nurse
- Drink at least 2 glasses of fluid (such as water), within a few hours before receiving Reclast, as directed by your doctor. You may eat normally before your infusion.

For Osteoporosis:

- Reclast is given once a year
- In women with osteoporosis, the current recommended daily intake of calcium is 1200 mg and vitamin D 400 IU to 800 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?

Possible serious side effects include:

- **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 kidney function 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 doctor.
- **Jaw-bone problems (Osteonecrosis of the jaw).** Jaw-bone problems may occur in some people and include: infection, delayed 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 in the days after you get Reclast. A mild pain reliever such as ibuprofen or acetaminophen may reduce these symptoms. The chance of getting these side effects goes down with repeat dosing of Reclast.

Tell your doctor 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 doctor.

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 doctor. You can ask your doctor 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 is a thinning and weakening of the 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 and with increasing age. People who have an increased risk of osteoporosis: 1) are white (Caucasian) or oriental (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) over a long 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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