

MEDICATION GUIDE

Reclast® (RE-clast)

(zoledronic acid)

Injection

Read the Medication Guide that comes with Reclast before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. Talk to your doctor if you have any questions about Reclast.

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

You should not receive Reclast if you are already receiving Zometa. Both Reclast and Zometa contain zoledronic acid.

Reclast can cause serious side effects including:

1. Low calcium levels in your blood (hypocalcemia)
2. Severe kidney problems
3. Severe jaw bone problems (osteonecrosis)
4. Bone, joint or muscle pain
5. Unusual thigh bone fractures

1. Low calcium levels in your blood (hypocalcemia).

Reclast may lower the calcium levels in your blood. If you have low blood calcium before you start taking Reclast, it may get worse during treatment. Your low blood calcium must be treated before you take Reclast. Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as:

- Spasms, twitches, or cramps in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood, while you take Reclast. Take calcium and vitamin D as your doctor tells you to.

2. Severe kidney problems.

Severe kidney problems may happen when you take Reclast. Your risk of kidney problems is higher if you:

- already have kidney problems
- take a diuretic or "water pill"
- do not have enough water in your body (dehydrated) before or after you receive Reclast

3. Severe jaw bone problems (osteonecrosis).

Severe jaw bone problems may happen when you take Reclast. Your doctor should examine your mouth before you start Reclast. Your doctor may tell you to see your dentist before you start Reclast. It is important for you to practice good mouth care during treatment with Reclast.

4. Unusual thigh bone fractures.

Some people have developed unusual fractures in their thigh bone. Symptoms of a fracture may include new or unusual pain in your hip, groin, or thigh.

5. Possible harm to your unborn baby.

Reclast should not be used if you are pregnant. Tell your doctor right away if you are pregnant or plan to become pregnant. Reclast may harm your unborn baby.

6. Bone, joint, or muscle pain

Some people who take bisphosphonates develop severe bone, joint, or muscle pain.

Call your doctor right away if you have any of these side effects.

What is Reclast?

Reclast is a prescription medicine used to:

- Treat or prevent osteoporosis in women after menopause. Reclast helps reduce the chance of having a hip or spinal fracture (break).
- Increase bone mass in men with osteoporosis.
- Treat or prevent osteoporosis in either men or women who will be taking corticosteroid medicines for at least one year.
- Treat certain men and women who have Paget's disease of the bone.

It is not known how long Reclast works for the treatment and prevention of osteoporosis. You should see your doctor regularly to determine if Reclast is still right for you.

Reclast is not for use in children.

Who should not take Reclast?

Do not take Reclast if you:

- Have low levels of calcium in your blood
- Are allergic to zoledronic acid or any of its ingredients. A list of ingredients is at the end of this leaflet.

What should I tell my doctor before taking Reclast?

Before you start Reclast, be sure to talk to your doctor if you:

- Have low blood calcium.
- Have kidney problems.
- Had parathyroid or thyroid surgery (glands in your neck).
- Have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome) or have had parts of your intestine removed.
- Have asthma (wheezing) from taking aspirin.
- Plan to have dental surgery or teeth removed.
- Are pregnant, or plan to become pregnant. Reclast may harm your unborn baby. **Reclast should not be used if you are pregnant.**
- Are breastfeeding or plan to breastfeed. It is not known if Reclast passes into your milk and may harm your baby.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Certain medicines may affect how Reclast works.

Especially tell your doctor if you are taking:

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

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

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

How will I receive Reclast?

- Your doctor will tell you how often you will receive Reclast.
- Reclast is given by infusion into your vein (intravenously). Your infusion should last 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 doctor.
- You may eat before your treatment with Reclast.
- If you miss a dose of Reclast, call your doctor or healthcare provider to schedule your next dose.

What are the possible side effects of Reclast?

Reclast may cause serious side effects.

- See “**What is the most important information I should know about Reclast?**”

The most common side effects of Reclast included:

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| • Fever | • Flu-like illness (fever, chills, bone, joint, or muscle pain, fatigue) |
| • Pain in your bones, joints or muscles | • Nausea |
| • Pain in your arms and legs | • Vomiting |
| • Headache | • Diarrhea |

Talk to your doctor about things you can do to help decrease some of these side effects that might happen with a Reclast infusion.

You may get allergic reactions, such as hives or, in rare cases, swelling of your face, lips, tongue, or throat.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Reclast. For more information, ask your doctor or pharmacist.

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

General information about safe and effective use of Reclast.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes 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 health 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 monohydrate

Inactive ingredients: mannitol and sodium citrate.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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