

MEDICATION GUIDE

Zoledronic Acid (ZOE-le-DRON-ik AS-id) Injection

Read the Medication Guide that comes with zoledronic acid injection 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 zoledronic acid injection.

What is the most important information I should know about zoledronic acid injection?

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

Zoledronic acid injection can cause serious side effects including:

- Low calcium levels in your blood (hypocalcemia)
- Severe kidney problems
- Severe jaw bone problems (osteonecrosis)
- Bone, joint or muscle pain
- Unusual thigh bone fractures

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

Zoledronic acid injection may lower the calcium levels in your blood. If you have low blood calcium before you start taking zoledronic acid injection, it may get worse during treatment. Your low blood calcium must be treated before you take zoledronic acid injection. 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 zoledronic acid injection. Take calcium and vitamin D as your doctor tells you to.

2. Severe kidney problems.

Severe kidney problems may happen when you take zoledronic acid injection. Severe kidney problems may lead to hospitalization or kidney dialysis and can be life-threatening. 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 zoledronic acid injection
- are of advanced age since the risk increases as you get older
- take any medicines known to harm your kidneys

You should drink at least 2 glasses of fluid within a few hours before receiving zoledronic acid injection to reduce the risk of kidney problems.

3. Severe jaw bone problems (osteonecrosis).

Severe jaw bone problems may happen when you take zoledronic acid injection. Your doctor should examine your mouth before you start zoledronic acid injection. Your doctor may tell you to see your dentist before you

start zoledronic acid injection. It is important for you to practice good mouth care during treatment with zoledronic acid injection.

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.

Zoledronic acid injection should not be used if you are pregnant. Tell your doctor right away if you are pregnant or plan to become pregnant. Zoledronic acid injection 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 zoledronic acid injection?

Zoledronic acid injection is a prescription medicine used to:

- Treat certain men and women who have Paget's disease of the bone.

Zoledronic acid injection is not for use in children.

Who should not take zoledronic acid injection?

Do not take zoledronic acid injection if you:

- Have low levels of calcium in your blood
- Have kidney problems
- 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 zoledronic acid injection?

Before you start zoledronic acid injection, 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. Zoledronic acid injection may harm your unborn baby.

Zoledronic acid injection should not be used if you are pregnant.

- Are breastfeeding or plan to breastfeed. It is not known if zoledronic acid injection 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 zoledronic acid injection works.

Especially tell your doctor if you are taking:

- An antibiotic. Certain antibiotic medicines called aminoglycosides may increase the effect of zoledronic acid injection 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 zoledronic acid injection?

- Your doctor will tell you how often you will receive zoledronic acid injection.
- Zoledronic acid injection is given by infusion into your vein (intravenously). Your infusion should last at least 15 minutes.
- Before you receive zoledronic acid injection, 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 zoledronic acid injection.

What are the possible side effects of zoledronic acid injection?

Zoledronic acid injection may cause serious side effects.

- See " **What is the most important information I should know about zoledronic acid injection?**"

The most common side effects of zoledronic acid injection included:

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

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

You may get allergic reactions, such as hives, 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 zoledronic acid injection. 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 zoledronic acid injection.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about zoledronic acid injection. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about zoledronic acid injection that is written for health professionals.

For more information, contact Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

What are the ingredients in zoledronic acid injection?

Active ingredient: zoledronic acid monohydrate

Inactive ingredients: mannitol and sodium citrate.

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

Zometa[®] is a trademark of Novartis.

Manufactured for:

Mylan Institutional LLC

Rockford, IL 61103 U.S.A.

Manufactured by:

Mylan Laboratories Limited

Bangalore, India

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