



## Taro-Zoledronic Acid for Treatment of Osteoporosis:

# What YOU should know



## What is Osteoporosis, and why does it need to be treated ?

Osteoporosis is a medical condition where bones become brittle, thin, and fragile. Over time, they can become so weak that they break more easily than normal. This condition is most common in women after menopause, but men may also develop osteoporosis. People whose bones are thinner than normal are said to have low bone mineral density.

Without treatment, osteoporosis can lead to bone fractures in the hips, spine, wrist, shoulder, and other bones of the body. These fractures can be very painful and cause weakness. Spinal fractures may cause loss of height and can affect the natural curvature of the spine.

Osteoporosis treatments work by slowing down the cells that cause thinning of bones and/or increasing the activity of cells that build up bones. The family of drugs most commonly used to treat osteoporosis is called bisphosphonates. Zoledronic acid, which is injected once a year, is the only injectable form of bisphosphonate treatment for osteoporosis.

## Who can benefit from zoledronic acid injection ?

Zoledronic acid injection has been the subject of many scientific studies, and it has been found useful for the prevention and treatment of osteoporosis in the following circumstances:

- Treatment of osteoporosis in postmenopausal women to reduce the risk of fracturing a hip, vertebra, and other bones when given once a year.
- Treatment to increase bone mineral density in men with osteoporosis when given once a year.
- Treatment and prevention of osteoporosis caused by glucocorticoid medicines such as prednisone in both men and women, when given once a year.
- Prevention of osteoporosis in postmenopausal women with low bone mass, given as a single treatment.
- Treatment of Paget's disease (another bone disease), given as a single treatment.

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## When might zoledronic acid injection be preferable to other medications to prevent and treat osteoporosis?

Most drugs used to treat osteoporosis are taken by mouth on a daily, weekly, or monthly basis. Zoledronic acid is delivered once a year by a type of injection called intravenous infusion. Some people find the once a year dosing schedule to be more convenient. In addition, there is no need to remember to take a pill or to add another pill for someone who is already taking many pills. In some cases, zoledronic acid may be used because individuals experience too many side effects from bisphosphonate tablets.



## Are there any individuals who should not use zoledronic acid injection?

You should not receive zoledronic acid injection if you:

- Have low calcium levels in your blood (hypocalcemia) or vitamin D deficiency
- Have severe kidney problems
- Are pregnant or plan to become pregnant
- Are breastfeeding
- Are allergic (hypersensitive) to zoledronic acid or any of the other ingredients in the zoledronic acid injection or to any other bisphosphonates

## How is zoledronic acid injection administered, and what is the dose

To receive zoledronic acid injection, you will need to visit an infusion clinic. A certified health professional will administer the drug as an intravenous infusion (also called a drip). The drug is administered slowly, usually over a 15-minute period through a needle placed in a vein. You will be asked to drink at least two glasses (500 mL or 2 cups) of water before and after the treatment. You may be asked to stay for a short period of time after the infusion as a precaution to ensure that you do not have a serious allergic reaction to the medication (a rare occurrence).

Zoledronic acid injection is given as a single dose of 5 mg (once only) to prevent osteoporosis or as a dose of 5 mg once yearly to treat osteoporosis.

## What side effects may occur with zoledronic acid injection?

Like all medicines, Taro-Zoledronic Acid may have some unwanted side effects in addition to its beneficial effects.

Zoledronic acid injection is administered by intravenous infusion. The most common side effects following zoledronic acid infusion are:

- Fever, chills, pain in the muscles or joints, headache, and other flu-like symptoms may occur in up to one-third of people receiving their first infusion. Symptoms usually appear within the first three days after infusion and go away on their own. Mild pain relievers such as ibuprofen or acetaminophen may be used to reduce the symptoms. Those who are receiving subsequent infusions have less risk of experiencing this reaction.

In addition, the following serious side effects have been noted:

- Fast and irregular heartbeat called atrial fibrillation is uncommon but may occur in some people. If you already have atrial fibrillation or have any other risk factors for the condition, you should speak with your doctor before getting the infusion.
- Orbital inflammation (inflammation around the eye) and inflammation in the eye (including conjunctivitis, uveitis, episcleritis, iritis, and scleritis) causing eye pain or disturbed vision may occur in 1% to 0.1% of people receiving zoledronic acid injection. You should speak with your doctor if you have an existing inflammatory eye condition or if you develop any symptoms such as painful red eye.
- Osteonecrosis of the jaw (numbness or feeling of heaviness in the jaw; poor healing of the gums especially after dental work; loose teeth; exposed bone in mouth; pain in the mouth, teeth, or jaw; swelling or gum infections; bad breath) has occurred rarely after zoledronic acid injection. Good oral hygiene and routine dental check-ups are recommended.
- Unusual thigh bone fracture has occurred very rarely in people using zoledronic acid injection for long periods of time. If you develop new or unusual pain in the thigh or groin, you should speak with your doctor.
- Additional serious side effects associated with zoledronic acid injection include low blood calcium (uncommon, causes numbness, tingling sensation especially in area around mouth, and muscle spasms), kidney failure (uncommon, causes weakness, tiredness, loss of appetite, puffy eyes/hands/feet, changes in urine colour or absence of urine production, changes in kidney function laboratory tests), and severe allergic reactions (very rare, cause rash, hives, swelling of the face/lips/tongue/throat, dizziness, difficulty swallowing or breathing, loss of consciousness due to shock).

A more complete list of possible side effects associated with zoledronic acid is available in the Taro-Zoledronic Acid Consumer Information leaflet.

## Are there drugs that shouldn't be taken at the same time as zoledronic acid injection?

Before using zoledronic acid injection, you should tell your doctor if you are taking any of the following medications:

- Any medication that could be harmful to your kidneys (e.g., nonsteroidal anti-inflammatory drugs or NSAIDs, such as ibuprofen and naproxen)
- Diuretics (water pills) such as hydrochlorothiazide and furosemide
- Aminoglycoside antibiotics such as gentamicin, tobramycin, and streptomycin
- Other drugs used to treat osteoporosis (especially other bisphosphonates such as etidronate, alendronate, and risedronate)

## Should I take extra calcium & vitamin D when receiving zoledronic acid?

Zoledronic acid can cause the levels of calcium in the blood to drop. Calcium is necessary for many important functions of the body, so you should ensure that you get enough calcium and vitamin D while using zoledronic acid.

Osteoporosis Canada recommends a daily intake of calcium of 1000 mg for individuals between 19 and 50 years of age and 1200 mg for those 50 years of age and older. Vitamin D recommendations are 400 IU to 1000 IU daily for people between 19 and 50 years of age and 800 IU to 2000 IU daily for those 50 years of age and older. Although it is better to get your calcium and vitamin D from the foods you eat, this isn't always possible. Talk with your doctor or pharmacist about whether you may need to take calcium and vitamin D supplements.

## Where can I get my zoledronic acid infusion?

To receive your zoledronic acid infusion, you will need to go to an infusion clinic. While you or your insurance plan will pay for the cost of the drug, the Taro-Zoledronic Acid Infusion Program provides your infusion services free of charge.

If your doctor has decided that treatment with zoledronic acid is right for you and you have a prescription or you have picked up your Taro-Zoledronic Acid from your pharmacy just call 1.833.618.0571, and the entire infusion service process will be arranged at a location that is most convenient for you.

