

medicineupdate

Asking the right questions about new medicines

Zoledronic acid (Aclasta) for osteoporosis

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get to know your medicines



National Prescribing Service Limited

NPS is an independent, non-profit organisation for Quality Use of Medicines, funded by the Australian Government Department of Health and Ageing.

Summary

Zoledronic acid (Aclasta) is a new treatment for osteoporosis that is used only once a year, and is given through a drip into a vein. It is an effective treatment for osteoporosis.

Zoledronic acid is a treatment option for people who may prefer a once a year treatment, or who can't take or tolerate other osteoporosis treatments.

Like all treatments for osteoporosis, it has a range of possible side effects — some minor and some serious. Some side effects last for a short time, while others may not go away quickly.

There have been clinical trials of zoledronic acid which studied its effects for two to three years. We do not know whether it continues to be effective and safe after three years.

1. What zoledronic acid is	The active ingredient of this medicine is zoledronic acid (pronounced ZOL-eh-DRON-ick AS-id). The brand name is Aclasta .	The active ingredient is the chemical in the medicine that makes the medicine work.
2. What zoledronic acid is for	Zoledronic acid is used to treat osteoporosis — a condition in which the bones become brittle and prone to breaking easily.	
3. How zoledronic acid is given	Zoledronic acid is given as an intravenous infusion — that is, it is put in through a drip into a vein in the arm — once a year. The infusion is given over at least 15 minutes. In most cases, this would be done by a nurse, and would be arranged by your doctor. The infusion may be given at your doctor's surgery, at an infusion centre or, in special circumstances, in your home. Occasionally, it may be given by your specialist.	
4. Who can use zoledronic acid	People can use zoledronic acid if they have been diagnosed with osteoporosis. It is available through the Pharmaceutical Benefits Scheme (PBS) for: <ul style="list-style-type: none">• women who have osteoporosis, and have had a bone break easily (e.g. after a minor bump or fall)• men who have osteoporosis and have had a hip break due to osteoporosis. On 1 April 2009, PBS eligibility for zoledronic acid was extended to include women with osteoporosis who have not yet had a bone break easily, but are at high risk of having one. To qualify, women must meet both of the following conditions: <ul style="list-style-type: none">• be aged 70 years or older• have a bone mineral density (BMD) T-score of minus 3.0 or worse.	Talk with your doctor about all of the treatment options for osteoporosis.

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4.
**Who can use
zoledronic acid**

A BMD scan, sometimes called a DXA scan, indicates the amount of calcium in your bones. This scan is quick and painless, like an X-ray. A BMD scan measures the density of your bones and compares the result to the bone density of an average young adult. The result is called a T-score. If you have osteoporosis your T-score will be minus 2.5 or lower. The lower your T-score the greater your risk of fracture, that is, a score of minus 3 is worse than a score of minus 2.5.

Zoledronic acid can be used by people who may prefer a once a year treatment, or who can't take or tolerate other osteoporosis treatments.

5.
**What does
zoledronic acid do?**

Our bones form and re-form throughout our lives. Cells in the bone are constantly being broken down and replaced by new ones. The bone as a whole remains much the same, but the individual cells making up the bone change.

In people with osteoporosis, the old bone cells are breaking down faster than the new bone cells are forming, so the bones become thin and break more easily.

Zoledronic acid slows the breakdown of some of the bone cells. Clinical trials have shown that it improves the strength of bones and can prevent fractures (broken bones).

6.
**Important side
effects to consider**

All medicines can have side effects. Sometimes, the side effects are serious but most of the time they are not. Some side effects are common, while others are very rare.

Zoledronic acid can cause some short-term side effects in the first few days after having the drip. These include nausea, vomiting, diarrhoea, fevers, muscle pain, headache, a flu-like illness, pain in the hands and feet, and pains in the joints. These side effects are much less common the second or third time you have the drip. Taking paracetamol soon after having the drip may reduce these side effects.

Rarely, severe pain can develop in the muscles, bones or joints. This pain can come on at any time after treatment, and may or may not go away.

Other rare but serious problems that can occur with zoledronic acid and similar osteoporosis medicines* include:

- breakdown of the bone of the jaw
- kidney problems
- eye problems.

You should discuss these possible side effects with your doctor and dentist to check if your health problems make you more likely to develop one of these problems.

*Like alendronate (e.g. Fosamax) and risedronate (e.g. Actonel).

For a list of possible side effects, see the consumer medicine information leaflet for Aclasta.

Ask your doctor about the possible side effects of this medicine before you use it.

Always tell your doctor about any changes to your condition if you are taking a new medicine.

You can also discuss side effects with a pharmacist, by calling the Adverse Medicines Event Line (see back page).

7.
What else you should know about zoledronic acid

Zoledronic acid has been available for a number of years in Australia. It has mainly been used at higher doses to strengthen bones in people with some types of bone cancer (under the brand name Zometa). But it has not been used much to treat osteoporosis until recently.

Zoledronic acid has been approved for use in Australia after undergoing the required testing.

Zoledronic acid is from the same family of osteoporosis medicines as alendronate (e.g. Fosamax) and risedronate (e.g. Actonel), but it is given only once a year. Once you have had an infusion of zoledronic acid, it stays in your bone for a long time. Other medicines in the same family that are taken as tablets also stay in your bone for a long time. If you have a side effect from it — particularly if the side effect is in your bone — it may stay for a long time.

You should talk to your doctor about other osteoporosis medicines. For example, you should continue to take calcium and vitamin D. But you should not continue to take medicines such as alendronate (Fosamax) and risedronate (Actonel).

You should discuss with your doctor any other treatments you are taking for osteoporosis before starting zoledronic acid.

8.
How to decide between zoledronic acid and other medicines

The main issues to consider when choosing between zoledronic acid and other treatments for osteoporosis are convenience and risk of side effects.

Remember that risks and benefits differ between medicines and from person to person.

Convenience

Some people may find it more convenient to have a treatment for osteoporosis once a year. Some people may also find it hard to sit upright, or to remember to take a medicine each week, as is needed with some other osteoporosis medicines.

On the other hand, having zoledronic acid means you have to have a drip into the vein, and some blood tests before the treatment. You also need to keep taking medicines such as calcium and vitamin D.

Side effects

Some side effects of zoledronic acid are the same as those of the other osteoporosis medicines, some occur because it is given as an infusion, and some side effects are unique to it. It is not known whether there is a greater or lesser risk of side effects than other osteoporosis medicines.

Zoledronic acid has not been used to treat osteoporosis for very long. It is known to have some minor but common side effects, as well as some serious side effects. These serious side effects are probably rare, but the medicine has not been used long enough to know this for sure. There is also the chance that some side effects will last for a long time.

It is possible that people having zoledronic acid will have less chance of irritation or burning of the oesophagus (food pipe) and stomach, which is common with many other forms of treatment for osteoporosis. This is because zoledronic acid is injected, not swallowed.

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8. How to decide between zoledronic acid and other medicines

Summary

A number of medicines have been shown to prevent fractures in people with osteoporosis. Most — like alendronate (e.g. Fosamax) and risedronate (e.g. Actonel) — are taken once a day or once a week by mouth. Some people might prefer zoledronic acid because it is a once a year treatment, or because they have difficulty taking the other treatments by mouth. Bear in mind that because zoledronic acid is a relatively new medicine, we know less about its long term side effects than we do for similar medicines such as alendronate and risedronate. We also do not know whether it continues to be effective after three years.

9. What does zoledronic acid cost?

As described in section 4, zoledronic acid is available through the Pharmaceutical Benefits Scheme (PBS) for:

- women who have osteoporosis and have had a bone break easily (e.g. after a minor bump or fall)
- men who have osteoporosis and have had a hip break due to osteoporosis
- women who are aged 70 years or older and have a bone mineral density (BMD) T-score of minus 3.0 or worse.

A maximum of three years of treatment is available through the PBS. After that time, you will have the choice of paying the full price for the medication or switching to a different treatment for osteoporosis.

If you are prescribed the once-a-year infusion of zoledronic acid through the PBS, you will need to pay a 'PBS co-payment'. At the time of publication, the co-payment was:

- \$31.30 for people without a concession card
- \$5.00 for concession card holders.

The full price to the Australian Government is about \$535.00 for each infusion.

Most medicines prescribed by your doctor are covered by the PBS. This means that the Australian Government pays part of the cost of your medicine.

You will need to pay the full price if the medicine is not available on the PBS, or is not available on the PBS for your specific condition.

10. Other ways to help osteoporosis

A healthy lifestyle — regular exercise, plenty of calcium in the diet, some sunshine and no smoking — is important for helping to prevent osteoporosis worsening and managing it.

Exercise

Exercise keeps muscles and bones strong and healthy. It also improves balance.

What type of exercise? Research shows that weight-bearing exercise such as brisk walking or dancing can help strengthen bones in some people. However, the main goal of exercise in people who already have weakened bones from osteoporosis is to improve their muscle strength and balance, to help prevent falls.

Exercises that are recommended if you have osteoporosis and fractures include Tai Chi, lifting weights, aqua aerobics and hydrotherapy. Improving your muscle strength and balance with these exercises means you may be less likely to fall and break a bone.

For more information, contact your local branch of Osteoporosis Australia (for details, go to www.osteoporosis.org.au or call 1800 242 141, which is a national toll free number).

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10. Other ways to help osteoporosis

If you have osteoporosis and fractures, avoid exercises which involve twisting, sudden severe movements and any activities that involve forward bending from the spine, particularly while carrying objects. Examples of activities to avoid include lawn bowls, sit-ups with straight legs or bending over to pick something off the floor with straight legs. These activities can all increase your risk of fractures in the spine.

Calcium

About 3–4 serves of dairy products each day are recommended.

One serve is:

- 250 mL glass of milk
- 200 g tub of yoghurt, or
- 40 g piece of cheese.

Canned fish, tofu, soy beans, other beans and green leafy vegetables such as broccoli and bok choy also contain good amounts of calcium. If you can't get enough calcium in your diet, then you may need to take a supplement as well.

Vitamin D — sunshine and diet

Vitamin D is also important as it helps the body to absorb calcium.

Sunshine helps your skin make vitamin D — about 15 minutes each day of sun in summer or 30 minutes each day of sun in winter on your face, arms and hands should be enough. This should be before 10 am or after 3 pm when the risk of sunburn is lowest. People who get little or no sunlight need a vitamin D supplement.

Vitamin D is also found in oily fish (such as tuna or mackerel), eggs and liver, and is added to some milks and margarines.

No smoking

Smoking thins your bones — quitting is extremely important, and not just for your bones. Call the Quitline on 131 848 if you want help.

Preventing falls

Reducing your chance of falling again may help you to prevent fractures. Your GP, physiotherapist or occupational therapist can help you work out your risk of falling and advise you about what you can do to keep yourself safe.

Where to find out more information

To find out more about this medicine

- Call the Medicines Line on 1300 888 763 to speak to a pharmacist (Mon–Fri, 9am–6pm EST for the cost of a local call, mobile calls more).
- Read the consumer medicine information (CMI) leaflet for this medicine.

The CMI will tell you:

- who should not take the medicine
- which medicines should not be taken at the same time (drug interactions)
- how to take the medicine
- most possible side effects
- the ingredients.

You can get the CMI leaflet for Aclasta from:

- your doctor or pharmacist
- www.nps.org.au/consumers
- Novartis, the makers of Aclasta, on 1800 671 203 or at www.novartis.com.au.

To report a side effect with zoledronic acid

Call the Adverse Medicine Events (AME) Line on 1300 134 237 (Mon–Fri, 9am–5pm EST).

The AME Line lets you report and discuss side effects that might be related to your medicine. The side effects of your medicine — but not your personal details — are reported to the Australian medicines regulatory agency (the Therapeutic Goods Administration or TGA for short). The information helps to improve the safe use of medicines.

For more information about the AME Line visit www.nps.org.au/ame_line.

More about taking medicines:

- How new medicines are tested and approved in Australia see NPS fact sheet 'New medicines: are they always better?' at www.nps.org.au/factsheets.
- Side effects: more information on understanding side effects is available from www.asmi.com.au.

What is *Medicine Update*?

Medicine Update lets you know about new drugs and new PBS listings. When medicines are new, we know less about their expected benefits and possible harms than we do for older medicines. It's important to understand what evidence is available about both benefits and harms. *Medicine Update* provides balanced information to help you decide if a medicine is right for you.

How to use *Medicine Update*

Medicine Update is a tool you can use to help understand your treatment choices and to discuss them with your doctor. *Medicine Update* doesn't describe all possible side effects or precautions, and you should always read the consumer medicine information (see above).

Who wrote *Medicine Update*?

National Prescribing Service Limited (NPS), an independent, non-profit, government-funded organisation, wrote this information in consultation with consumers and health professionals.

Date published: December 2008

Updated: March 2009

Visit the NPS website to find out about our free activities and resources
for consumers www.nps.org.au/consumers



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National Prescribing Service Limited (NPS) is an independent, non-profit organisation for Quality Use of Medicines, funded by the Australian Government Department of Health and Ageing.

This review was conducted by the National Prescribing Service Limited (NPS) in consultation with consumers and health professionals.