

medicineupdate

Asking the right questions about new medicines

Strontium ranelate (Protos) – for osteoporosis in postmenopausal women

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get to know your medicines

to find out more about this medicine

- call Medicines Line on 1300 888 763 to speak to a pharmacist (Mon-Fri 9am-6pm EST – cost of a local call, mobile calls more)
- read the Consumer Medicine Information (CMI) for this medicine (available from your doctor or pharmacist, the consumer section at www.nps.org.au, or from the manufacturer).



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.

When you are considering a new medicine, it is important to weigh up the expected benefits and the possible risks of the new medicine, compared with other available medicines or treatments.

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

Your doctor can help you compare different medicines and treatments to decide what is best for your particular situation.

1.
What this medicine is

The active ingredient is **strontium ranelate** and the brand name is **Protos**.

It is pronounced STRON-tee-um RAN-ell-ate, or PRO-toss.

It comes as a powder that you dissolve in water and take once a day.

The active ingredient is the chemical in the medicine that makes the medicine work.

2.
What this medicine treats

Strontium ranelate treats osteoporosis.

Osteoporosis is a condition which causes bones to become fragile and brittle. If you have osteoporosis you are at risk of fractures (broken bones), most commonly in the hips, spine (backbone) and wrists. These fractures can cause long-term pain and the loss of independence.

Osteoporosis is more common in women, especially after menopause, but it can occur in men. Osteoporosis may also be caused by long-term use of some medicines, such as prednisolone, that are used for asthma and some rheumatic conditions.

Osteoporosis medicines are most useful for people who have a high risk of fracturing their bones. People who have already had a fracture have the greatest risk of having another fracture. People who are older and have thinner bones (technically known as lower bone mineral density) also have a greater risk of fracturing their bones and can benefit from osteoporosis medicines.

Strontium works by slowing the thinning of the bones and by allowing new bone to rebuild and strengthen. Bone strength is usually measured by a bone mineral density scan, which indicates the amount of calcium in your bones. A bone mineral density scan is also sometimes called a BMD scan or a DEXA scan. This scan is quick and painless, like an X-ray.

A bone mineral density 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. A score of minus 3 is lower (worse) than a score of minus 2.5. The lower your T-score the greater your risk of fracture.

Treatment with strontium aims to reduce your risk of fracturing your bones and to increase your bone mineral density.

3.
**Who can use
this medicine?**

Women who have passed menopause (i.e. postmenopausal women) can use strontium ranelate to treat osteoporosis. You can receive strontium which is subsidised by the Pharmaceutical Benefits Scheme (PBS) if:

- you have already had a fracture due to postmenopausal osteoporosis
or
- you are 70 or older and have a T-score on your bone mineral density test of minus 3 or lower.

Strontium should not be prescribed to men, or to women who have not passed menopause (i.e. pre-menopausal women). It has not been tested in these groups.

4.
**Other medicines
available for this
condition**

Other medicines apart from strontium ranelate are available in Australia for the treatment of osteoporosis. They include:

- alendronate (Fosamax Plus, Alendro Once-weekly, Alendrobell and Ossmax), etidronate (Didronel, Didrocal) and risedronate (Actonel), which all belong to a group of medicines called bisphosphonates
- raloxifene (Evista), which has similar effects on bone to oestrogen
- teriparatide (Forteo), which is a synthetic form of a hormone normally produced by the parathyroid gland (which sits near the thyroid gland in the throat).

Hormone replacement therapy (HRT), or oestrogen therapy, was once widely used for women with postmenopausal osteoporosis. It is no longer recommended for the sole purpose of reducing the risk of fracture (especially in older women) because of some serious side effects that may happen after long term use.

All these medicines work in different ways.

Not all of these other medicines are subsidised on the PBS for people with osteoporosis. Raloxifene can be prescribed through the PBS for postmenopausal women who have had a fracture due to osteoporosis. Alendronate and risedronate can be prescribed through the PBS for men and women with osteoporosis who:

- have already had a fracture due to osteoporosis
or
- are 70 or older and have a T-score on a bone mineral density test of minus 3 or less.

**Talk with your
doctor about all
of the treatment
options for
osteoporosis.**

5.
How well it works compared with other medicines

Alendronate, risedronate or strontium ranelate may all be used by women with postmenopausal osteoporosis. However, because strontium is a newer medicine, doctors and pharmacists have less experience using it and its long-term safety is less established.

Strontium has not been directly compared in the same clinical trial with any other medicine used for the treatment of osteoporosis, so it is hard to say exactly how they compare. All of the trials of strontium have involved postmenopausal women (average age about 74 years). No clinical trials have looked at the effectiveness of strontium for men or premenopausal women.

There are clinical trials that show that strontium reduces the risk of a fracture when compared to a placebo (dummy pill). Other clinical trials show that alendronate and similar medicines also reduce the risk of a fracture compared with placebo. Looking at this research, it seems that strontium reduces fractures in the spine by about the same amount as alendronate for women who have already had a fracture, as well as for women aged 70 and older with low bone mineral density but no previous fracture. There is also some research showing that strontium reduces the risk of fractures in women aged over 80.

There is evidence that alendronate and risedronate may reduce the risk of hip fracture. While there is also evidence that strontium may reduce the risk of hip fracture for postmenopausal women, more research is needed on this question.

A clinical trial is a research study conducted with patients, which compares one treatment with one or more other treatments, or with no other treatment, to assess its effectiveness and safety. For more information see Section 11: How new medicines are tested and approved for use in Australia.

6.
Important side effects to consider

Strontium ranelate is a new medicine, so we know little about its long-term side effects and safety beyond five years of use.

All medicines can have side effects. Sometimes the side effects are serious but most of the time they are not.

The most common side effects of strontium are nausea, diarrhoea, headache and rashes. These usually settle down fairly quickly.

Serious but uncommon side effects include a risk of clots forming in the legs or lungs — women who have had blood clots previously should discuss this with their doctors before taking strontium.

Problems such as memory loss, poor concentration and fits were reported in some clinical trials of strontium, but these were rare.

Strontium may also cause a serious type of allergic reaction involving a rash. If you are taking strontium and develop a rash, you should stop taking the medicine immediately and see your doctor.

For a list of possible side effects, see the Consumer Medicine Information leaflet for Protos.

Talk to 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.

More information on understanding side effects is available from the Australian Self-Medication Industry at www.asmi.com.au

7. How these side effects compare with other medicines

More is known about the side effects and long-term safety of other treatments for osteoporosis.

Bisphosphonates (eg. Actonel, Alendro Once-weekly, Didrocal, Didronel and Fosamax Plus): Common side effects of bisphosphonates are nausea, vomiting, diarrhoea, muscle pain, joint pain and headache. Damage to the oesophagus (or gullet) and inflammations of the stomach and digestive system can occur, so taking these medicines when and as directed is important to help prevent these effects.

Less common side effects that can occur are an inflamed tongue or eyes and, rarely, an allergic reaction.

A rare but important side effect of bisphosphonates is damage to the jaw bone, which can come on slowly and may not heal even if the medicine is stopped. Symptoms can vary and include severe jaw pain, numbness, infections, bad breath, sore teeth, denture sore spots, loose teeth and slow healing of cuts or infections. Most cases have occurred in people with cancer taking high doses of these medicines by injection, and the risk in people taking tablets for osteoporosis is relatively small. Taking good care of your teeth and gums may help to avoid this adverse effect.

Raloxifene (Evista): Common side effects of raloxifene are hot flushes, sweating, leg cramps, fluid retention and sleep problems. A serious side effect is blood clots — if you have had blood clots in the past, you should not take raloxifene.

Teriparatide (Forteo): The side effects of teriparatide are nausea, headache, dizziness, leg cramps, joint pain and high levels of uric acid in the blood (which may make you susceptible to gout).

Hormone replacement therapy (HRT): Common side effects of HRT are nausea, headache, breast pain, vaginal bleeding, changes in weight and leg cramps. Women who have not had a hysterectomy have to take another type of hormone — called a progestogen — to help prevent cancer of the uterus, which may occur if oestrogen is used on its own. This combination of HRT increases the risk of blood clots, heart disease, stroke and breast cancer, so it is not recommended for long-term use for osteoporosis. Oestrogen therapy on its own can also increase the risk of stroke, blood clots and breast cancer. These serious adverse effects of HRT are more likely to occur in older postmenopausal women, mostly over the age of 60 years.

8.
What else you should know about this medicine

Take strontium at bedtime, at least two hours after last eating or drinking milk. You take it each day. Take strontium by dissolving the powder in at least 30 mL of water (about a third of a glass).

Calcium in food and drink can reduce how much strontium ranelate is absorbed by the body. If you take calcium supplements, tetracyclines (a type of antibiotic) or antacids as well as strontium, you should take them at a different time of day (at least two hours before strontium).

You should also read the Consumer Medicine Information leaflet. The Consumer Medicine Information leaflet will tell you:

- who should and who should not take the medicine
- which medicines should not be taken while taking strontium
- how to take the medicine
- the most likely side effects
- the ingredients.

You can get the Consumer Medicine Information leaflet for Protos from:

- your doctor or pharmacist
- www.nps.org.au/consumers (click on 'Consumer Medicine Information' in the Quicklinks column on the left of the screen)
- Servier, the makers of Protos, on 1800 153 590 or www.servier.com.au

Consumer Medicine Information leaflets are available for most prescription medicines.

9.
Who can be prescribed this medicine on the Pharmaceutical Benefits Scheme (PBS)

You can only be prescribed one osteoporosis medicine through the PBS at a time. So you cannot be prescribed strontium ranelate through the PBS if you are already taking a PBS-subsidised medicine for osteoporosis.

Strontium is subsidised on the PBS for use by some postmenopausal women with osteoporosis. You are eligible:

- if you have already had a fracture due to osteoporosis
or
- if you are 70 or older and have a T-score on your bone mineral density test of minus 3 or lower.

The full cost of each strontium prescription is \$52.10. But if you are prescribed strontium through the PBS, you pay only the cost of a normal prescription, and the Australian government pays the rest. At the time of publication, the cost of a normal prescription was:

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

Each prescription lasts 28 days, and you can get up to five repeats.

Most medicines prescribed by your doctor are covered by the Pharmaceutical Benefits Scheme. 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 Pharmaceutical Benefits Scheme, or is not available on the Pharmaceutical Benefits Scheme for your specific condition.

10. Other ways to help this condition

A healthy lifestyle — regular exercise, plenty of dietary calcium, some sunshine and no smoking — is important for helping to prevent osteoporosis and to manage it along with your medications.

Exercise

Exercise maintains bone mass and improves muscle strength and balance.

Research shows that weight-bearing exercise such as 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 muscle strength and balance. Exercises that are recommended if you have osteoporosis include Tai Chi, aquaerobics and hydrotherapy. Improving your muscle strength and balance with these exercises means you may be less likely to fall and break a bone. Avoid high-impact exercises that may break a bone, such as those involving twisting, sit-ups or sudden muscle movements (e.g. lifting weights).

Dairy products

About 3–4 serves of dairy products each day is recommended. A 250 mL glass of milk, a 200 g tub of yoghurt and a 40 g piece of cheese are each one serve. Canned fish, tofu, some beans and some green vegetables also contain good amounts of calcium. If an adequate daily intake cannot be achieved in the diet, a calcium supplement is needed.

Vitamin D and sunshine

Vitamin D is also important as it helps the body absorb calcium. Sunshine helps your skin make vitamin D – about 15 minutes of sun on your face, arms and hands on most days of the week should be enough, preferably before 10 am or after 3 pm when the risk of sunburn is lowest. Vitamin D is also found in oily fish (such as tuna or mackerel), eggs and liver, and is added to some milks and margarines. The diet is unlikely to provide an adequate daily intake on its own, so people who get little or no sunlight need a vitamin D supplement.

Quitting smoking

Smoking thins your bones – quitting is a good idea. Call the Quitline on 131 848 if you'd like help.

Reducing your risk of falling over may help you to prevent a fracture. Your GP, physiotherapist or occupational therapist can help you assess your risk of falling and advise what you can do to keep yourself safe.

For more
information, contact
Osteoporosis Australia:
www.osteoporosis.org.au
on 1800 242 141 for
the branch details
in your state.

11.

How new medicines are tested and approved for use in Australia

Prescription medicines go through many tests and clinical trials before they can be prescribed in Australia. All medicines go through four types of tests to assess their effectiveness, side effects and safety:

- **laboratory tests** (not involving people)
- **phase 1** clinical trials, typically with 20–80 healthy volunteers, to test the safety and dosage in people with normal physical health
- **phase 2** clinical trials, typically with 100–500 volunteers with the condition, to test the effectiveness and safety
- **phase 3** clinical trials, typically with 1000–3000 volunteers with the condition, to confirm the medicine's effectiveness and find out more about its side effects.

Sometimes, less common side effects do not become obvious until large numbers of people have used the medicine.

The Therapeutic Goods Administration (Australia's regulatory agency for medicines) checks clinical trial results before it approves the registration of the medicine for use in Australia.

Medicines are made available on the Pharmaceutical Benefits Scheme if they are shown to be as good as or better than other available medicines for the same condition.

Why Medicine Update?

Medicine Update lets you know about new drugs and new PBS listings. When medicines are new, less is known about their expected benefits and possible harms than 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.

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.

Who is it for?

Medicine Update is written for people who are thinking about a new medicine, or have had a medicine suggested or prescribed for them and want to find out more.

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



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