

PROTOS[®] 2g

Strontium ranelate (pronounced stron-tee-um ran-ell-ate)

What is in this leaflet

This leaflet answers some common questions about PROTOS. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of taking PROTOS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PROTOS is

The name of your medicine is PROTOS. The medicine contains the active ingredient strontium ranelate. PROTOS does not contain any hormones.

What PROTOS is used for

You may be prescribed PROTOS for osteoporosis.

PROTOS is available only with a doctor's prescription.

There is no evidence that PROTOS is addictive.

Why PROTOS is used for osteoporosis

Bone is a living tissue just like most other parts of your body. Your body is constantly breaking down old bone and making new bone tissue to keep your skeleton healthy and strong.

When you have osteoporosis, your body breaks down more bone than it forms. Bone loss then gradually occurs making your bones thinner and more fragile.

Osteoporosis is especially common in women after the menopause (change of life). The menopause occurs when the ovaries stop producing the female hormone oestrogen, or are removed (sometimes with a hysterectomy). The earlier a woman reaches menopause, the greater the risk of osteoporosis.

Many people with osteoporosis have no symptoms so you may not even have been aware that you have it. However, osteoporosis makes you more likely to have fractures (break bones), especially in your spine, hips and wrists. A fracture may even occur during normal everyday activity, such as lifting or from other activities or strains that would not normally be sufficient to break bone.

Although fractures usually cause pain, fractures of the bones of the spine may go unnoticed until they cause loss of height and a curved back.

Ask your doctor if you have any questions about why PROTOS has been prescribed for you.

Before you take PROTOS

There are some people who should not take PROTOS. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please consult your doctor or pharmacist.

Do not take PROTOS if:

- You are allergic to strontium ranelate or any of the other ingredients of PROTOS listed at the end of this leaflet.
- You have previously experienced an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash)- discuss this with your doctor before taking PROTOS.
- You are pregnant or trying to become pregnant.
- You are breastfeeding or plan to breast-feed.
- You have severe kidney disease.
- The packaging is torn or shows sign of tampering.
- The expiry date (EXP) on the pack has passed.

Take special care with PROTOS:

- If you are being treated, or have been treated, for blood clots.
- If you are confined to bed or if you are to undergo an operation that subsequently requires a period of bed rest. The risk of vein thrombosis (blood clots in the leg) may be increased in the event of lengthy immobilisation.

PROTOS contains aspartame. If you suffer from phenylketonuria (a rare, hereditary disorder of the metabolism) talk to your doctor before you start to take this medicine.

Tell your doctor straight away if:

- You become pregnant while you are taking PROTOS.
- You are allergic to any other medicines or any foods, dyes, or preservatives.
- You experience pain or swelling in the legs or unusual or sudden shortness of breathe.
- You experience an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash). In any of these cases you must stop taking PROTOS and get medical advice immediately.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket, or health food shop.

PROTOS is unlikely to interact with other medicinal products. However, it is recommended that if you are taking tetracycline or quinolone (types of antibiotics) you temporarily stop taking PROTOS while you are taking the antibiotic. You may continue taking PROTOS after you have stopped the antibiotic treatment.

If you are taking drugs containing calcium, you should wait at least 2 hours between a dose of these medicines and taking PROTOS.

Your doctor may advise you to take calcium and vitamin D supplements in addition to PROTOS. You should wait at least 2 hours between a dose of calcium and taking PROTOS.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking PROTOS.

For older people or children

- Elderly people can generally use PROTOS safely.
- PROTOS is not recommended for use in children.

How to take PROTOS

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

PROTOS is for oral use.
The usual dose of PROTOS is one 2g sachet a day.
It is recommended that you take PROTOS at bedtime. Take PROTOS at least two hours

after eating or drinking milk or milk products as these may interfere with absorption. PROTOS can also be taken on an empty stomach.
You may continue your usual activity – sitting, standing or lying down after taking PROTOS. Take PROTOS as a suspension in a glass containing a minimum of 30ml (approximately one third of a standard glass) of water (see instructions below). PROTOS can interact with milk products, so it is important that you mix it only with plain water.



1. Empty the powder from the sachet into a glass;



2. Add water;



3. Stir until the powder is evenly dispersed in the water.

4. Drink straight away.

If for some reason you do not drink the medicine straight away, make sure you stir it again before drinking. You should not leave it more than 24 hours before you drink it.

Do not take calcium supplements at the same time as PROTOS.

How long to take PROTOS for

Your doctor will tell you how long you should continue to take PROTOS for. Osteoporosis therapy is usually required for a long period. It is important that you continue taking PROTOS for as long as your doctor prescribes the medicine.

If you forget to take PROTOS

If it is almost time for your next dose, just take your next dose at the usual time and don't worry about the missed sachet. If you realize you have missed a dose of PROTOS some time before the next dose is due then take your PROTOS as soon as you remember, and then continue taking it as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much PROTOS
If you think you or anyone else may have taken too much PROTOS then act immediately.

Telephone your doctor, pharmacist or the Poisons Information Centre (telephone in Australia: 13 11 26; in New Zealand: 0800 764 766) if you think you or anyone else may have taken too much PROTOS. **Do this even if there are no signs of discomfort or poisoning.**

While you are taking PROTOS

Things you must do

Take PROTOS exactly as your doctor has prescribed. Otherwise you may not get the full benefits from treatment.

Tell all doctors, dentists and pharmacists involved with your treatment that you are taking PROTOS.

If you experience an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash), you must stop taking PROTOS and seek medical advice immediately. If you have stopped treatment due to an allergic reaction you should not start taking PROTOS again

Things you must not do

Do not give PROTOS to anyone else, even if they have the same condition as you.

Do not use PROTOS to treat other complaints unless your doctor tells you to.

Do not stop taking PROTOS or change the dosage, without checking with your doctor.

Do not continue to take PROTOS if you have an allergic reaction to this medicine. If you have had an allergic reaction to PROTOS do not start taking this medicine again.

Side effects

If you do not feel well while you are taking PROTOS then tell your doctor or pharmacist as soon as possible.

All medicines can have side effects. Most of the time they are not serious but sometimes they can be.

PROTOS helps most people with osteoporosis, but it may sometimes have unwanted side effects. These can include:

- nausea,

- diarrhoea,
- headache,
- muscle pain and
- allergic reactions including rash and fever, itching, hives, swollen face, swollen tongue or swollen throat and/or difficulty in breathing or swallowing.

These side effects are usually mild when they occur. Do not be alarmed by this list of possible side effects. You may not experience any of them. However if you do - or if you notice anything else that is making you feel unwell - you should consult your doctor or pharmacist.

If you experience an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, or skin rash), you must stop taking PROTOS and seek medical advice immediately. If you have stopped treatment due to an allergic reaction you should not start taking PROTOS again.

An uncommon side effect of PROTOS is a blood clot in a vein (thrombosis). You should consult your doctor at once if you experience pain or swelling in the legs or unusual or sudden shortness of breath.

After taking PROTOS

Storage

Keep your PROTOS sachets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your sachets sealed and in the pack until it is time to take them. PROTOS will not keep as well outside its sachet packaging.

Heat and dampness can destroy some medicines. Keep them in a cool, dry place where the temperature stays below 30°C. Do not store medicines in a bathroom or near a sink. Do not leave them in a car or on a windowsill.

Disposal

If your doctor tells you to stop taking PROTOS, or the sachets have passed their expiry date, return any leftover sachets to your pharmacist for disposal.

What PROTOS looks like

PROTOS comes in sachets containing a yellow powder (consisting of small granules) for oral suspension. PROTOS is supplied in boxes of 7 or 28 sachets.

Ingredients

Each sachet of PROTOS 2g contains 2g of strontium ranelate as the active ingredient and a number of inactive ingredients.

The inactive ingredients include aspartame (E 951), maltodextrin, mannitol. Aspartame contains a source of phenylalanine.

PROTOS is gluten and lactose-free.

Manufacturer

PROTOS is a product developed by Servier Research International.

It is distributed in Australia by:
Servier Laboratories (Aust) Pty Ltd
8 Cato Street
Hawthorn Victoria 3122
ABN: 54 004 838 500

The New Zealand contact address for Servier Laboratories is:
Servier Laboratories (New Zealand) Ltd
12th Floor, Citibank Building
23 Customs Street
Auckland

PROTOS is registered on the Australian register of Therapeutic Goods.

Australian Register Number:

PROTOS 2g sachets: AUST R 99978

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