

PROTOS[®] 2g

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

Consumer Medicine Information

Warning: PROTOS should only be used when other medications for the treatment for osteoporosis are considered unsuitable. PROTOS must not be used in patients with established, current or past history of: ischaemic heart disease, peripheral vascular disease, cerebrovascular disease, uncontrolled hypertension, venous thromboembolism, pulmonary embolism. It should also not be used in patients who are temporarily or permanently immobilised. PROTOS should be used with caution in patients with risk factors for cardiovascular events or venous thrombosis: hypertension, diabetes, smoking, hyperlipidaemia. Your doctor will inform you of the risk of cardiovascular events and venous thrombosis, and that you will be regularly monitored every 6 months. Please refer to the section 'Before you take PROTOS' in this document for more information. Ask your doctor or pharmacist if you have any questions.

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 medications have risks and benefits. Your doctor has considered this before prescribing PROTOS for you.

If you have any concerns about taking this medication, 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

PROTOS is usually prescribed for severe (established) osteoporosis.

Osteoporosis is a disease of older people.

PROTOS should only be used when other medications for the treatment for osteoporosis are considered unsuitable (e.g. because your doctor has told you that you should not take other medications prescribed for osteoporosis, or because you may have had a side effect with other medications prescribed for osteoporosis).

PROTOS is not recommended for children, or pregnant women.

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.

PROTOS helps by increasing new bone formation and slowing bone breakdown. 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.

Osteoporosis can also occur in men.

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/or 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.

- If you have previously experienced an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash).
- If you suffer from Phenylketonuria (a rare, hereditary disorder of the metabolism) as PROTOS contains aspartame.
- If you are being treated, or have been treated, for blood clots.
- If you have risk factors for cardiovascular events e.g. high blood pressure, diabetes, smoking, high cholesterol. PROTOS should be used with caution. Your doctor will be able to discuss these risk factors with you.
- If you have ischaemic heart disease or cerebrovascular disease e.g. you have been diagnosed with angina, heart attack, stroke, or transient ischaemic attack (temporary reduction of blood flow to the brain also known as "mini-stroke"), or blockages of blood vessels to the heart or brain).
- If you have had problems with your blood circulation (peripheral arterial disease) due to obstruction of your large blood vessels e.g. in your legs.
- If you have high blood pressure where your systolic blood pressure is greater than or equal to 160 mmHg, or diastolic blood pressure is greater than or equal to 90 mmHg. even after treatment.

Do not take PROTOS if:

- You have severe kidney disease that reduces the function of your kidneys.
- You are allergic to strontium ranelate or any of the other

ingredients of PROTOS listed at the end of this leaflet.

- You are pregnant or trying to become pregnant.
- You are breastfeeding or plan to breast-feed.
- The packaging is torn or shows sign of tampering.
- The expiry date (EXP) on the pack has passed.

Before you start taking PROTOS, and then regularly every six months while you are taking PROTOS, your doctor will check whether you have any of the following cardiovascular risks. Do not take PROTOS if you have any of these risks:

- If you have ischaemic heart disease or cerebrovascular disease e.g. you have been diagnosed with angina, heart attack, stroke, or transient ischaemic attack (temporary reduction of blood flow to the brain also known as "mini-stroke"), or blockages of blood vessels to the heart or brain)
- If you have high blood pressure where your systolic blood pressure is greater than or equal to 160 mmHg, or diastolic blood pressure is greater than or equal to 90 mmHg even after treatment
- If you have had problems with your blood circulation (peripheral arterial disease) due to obstruction of your large blood vessels e.g. in your legs
- You have or have had a blood clot (for example, in the blood vessels in your legs or lungs)
- You are immobilised. The risk of vein thrombosis (blood clots in the leg or lungs) may be increased in the event of lengthy immobilisation, for example, undergoing an operation or recovering from an operation; or being wheel-chair bound; or confined to bed.

Tell your doctor straight away if:

- You are about to undergo an operation that subsequently requires a period of bed rest
- If you have previously experienced an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash)
- If you have ischaemic heart disease or cerebrovascular disease e.g. you have been diagnosed with angina, heart attack, stroke, or transient ischaemic attack (temporary reduction of blood flow to the brain also known as "mini-stroke"), or blockages of blood vessels to the heart or brain)
- If you have had problems with your blood circulation (peripheral arterial disease) due to obstruction of your large blood vessels e.g. in your legs
- If you have high blood pressure where your systolic blood pressure is greater than or equal to 160 mmHg, or diastolic blood pressure is greater than or equal to 90 mmHg. even after treatment.

Taking other medicines

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

PROTOS is unlikely to interact with other medications. It is recommended that if you are taking a tetracycline or a quinolone (types of antibiotics such as minocycline, doxycycline, norfloxacin and ciprofloxacin hydrochloride) you temporarily stop taking PROTOS while you are taking the antibiotic. You may continue taking PROTOS after you have stopped the antibiotic treatment.

Your doctor may advise you to take calcium and vitamin D supplements as well as PROTOS.

Discuss with your doctor or pharmacist whether any of the other medications you take contain calcium. See the section "How to take PROTOS" for advice about taking PROTOS and calcium-containing products.

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

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 can be taken on an empty stomach. You may continue your usual activity - sitting, standing or lying down after taking PROTOS.

For PROTOS to work well it is best to take it at least two hours before or at least two hours after food (especially milk products) or medications containing calcium (such as calcium tablets).

You may find it convenient to take PROTOS at bedtime. Some patients say they find it convenient to take it during the night if they get up to go to the bathroom.

PROTOS is for oral use.

The usual dose of PROTOS is one 2 g sachet per day. Just follow these four simple steps:

Step 1.

Empty the powder from the sachet into a glass.

Step 2.

Add a minimum of 30mL of plain water (approximately one third of a standard glass). Do not use boiling water or milk products.

Step 3.

Stir until the powder is evenly mixed in the water. Not all the powder will

dissolve and it will have a milk-like appearance.

Step 4.

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

Don't forget it is best to wait at least two hours before taking food, milk products or medications containing calcium, for PROTOS to work well.

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 medication.

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 realise 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 as your doctor has prescribed otherwise you may not get the full benefits from treatment.

While you are taking PROTOS, every six months your doctor will check whether you have any of the cardiovascular risks mentioned previously in the 'do not take PROTOS if' section of this document.

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

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 medication. If you have had an allergic reaction to PROTOS do not start taking this medication again.

Unwanted effects

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

All medications can have unwanted effects in some people. Sometimes they are serious but most of the time they are not.

PROTOS helps most people with osteoporosis, but it may sometimes have unwanted effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Nausea, vomiting, diarrhoea, stomach pain or discomfort, irritation in the mouth (such as mouth ulcers and sore gums). If you do experience diarrhoea, it is advisable to avoid taking any laxatives (medicines which assist bowel movements or treat constipation). Ask your doctor or pharmacist if you are unsure
 - Skin rash, unusual hair loss
 - Headache, feeling confused, memory trouble, dizziness, or vertigo
 - insomnia
 - Bone, muscle and/or joint pain and muscle cramps, swelling of hands, ankles or feet. Pins and needles
 - Feeling excessively tired, looking pale, getting frequent infections and bleeding and bruising easily may be signs of reduced red or white blood cells or platelets (Bone Marrow Depression)
 - Right side stomach pain and/or a general feeling of unwell with nausea, vomiting, loss of appetite, fever, itching and dark coloured urine; with or without jaundice (yellowing of the skin and eyes)
 - Heart attack (chest pain, or chest pain which may spread to the neck and shoulders)
 - An increase in your cholesterol levels.
- Do not be alarmed, you may not experience anything on this list. Other unwanted effects have been reported and you should ask your doctor or pharmacist if you want to know more.
- See your doctor if you experience any of these or notice anything else that is making you feel unwell.**
- Ask your doctor or pharmacist if you don't understand something in this list.**
- If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**
- Wheezing and shortness of breath (the medical term for this is bronchial hyper-reactivity)
 - Rash - may be the first sign of rare life threatening conditions (e.g. Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and severe hypersensitivity reactions (DRESS)). Although still rare, there have been more reports of these events in patients of Asian origin than in patients of non-Asian origin. The risk of these skin reactions in patients of Asian origin, particularly Han Chinese, may be predicted. Patients who have the HLA-A*33:03 and/or the HLA-B*58:01 genes are more likely to develop a serious skin reaction than those who do not have the genes. Your doctor should be able to advise if a blood test is necessary before taking PROTOS
 - The highest risk of SJS and TEN is within the first weeks of treatment and about around 3-6 weeks for DRESS
 - SJS and TEN start initially with a rash - reddish target-like spots or circular patches often with blisters and may be accompanied by flu-like symptoms, conjunctivitis and ulcers in the mouth and on genitals. The rash may progress to widespread blistering or peeling of the skin
 - DRESS may appear as a rash on the face which may extend to other parts of the body, flu-like symptoms and a high temperature
 - If you experience one or more of the unwanted effects associated with SJS, TEN or DRESS you must stop taking PROTOS and seek medical advice immediately. If you have stopped treatment due to SJS, TEN or DRESS this must be permanent and you should not start taking PROTOS again
 - A blood clot in a vein (the medical term for this is Thrombosis). Postmenopausal women with osteoporosis,

whether or not taking PROTOS may commonly experience thrombosis. You should consult your doctor at once if you experience pain, and redness or swelling in your legs or unusual or sudden shortness of breath

- You experience chest pain, or chest pain which may spread to the neck and shoulders). These may be signs that you might be having a heart attack.

After taking PROTOS

Storage

Keep your PROTOS sachets where children cannot reach them.

A locked cupboard is a good place to store your medication.

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 medications. Keep them in a cool, dry place where the temperature stays below 30°C. Do not store medications 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 2 g contains 2 g 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

The New Zealand contact address for Servier Laboratories is:

Servier Laboratories (New Zealand)
Ltd
Level 4, Zurich House
21 Queen Street
Auckland Central
Auckland 1010

PROTOS is registered on the Australian register of Therapeutic Goods.

Australian Register Number:
PROTOS 2 g sachets: AUST R
99978

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