

Package leaflet: Information for the patient

PROTELOS 2 g granules for oral suspension Strontium ranelate

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What PROTELOS is and what it is used for
2. What you need to know before you take PROTELOS
3. How to take PROTELOS
4. Possible side effects
5. How to store PROTELOS
6. Contents of the pack and other information

1. What PROTELOS is and what it is used for

PROTELOS is a medicine used to treat severe osteoporosis:

- in postmenopausal women,
- in adult men,

at high risk of fracture, for whom other alternative treatments are not possible. In postmenopausal women, strontium ranelate reduces the risk of fracture at the spine and at the hip.

About osteoporosis

Your body is constantly breaking down old bone and making new bone tissue. If you have osteoporosis, your body breaks down more bone than it forms so that gradually bone loss occurs and your bones become thinner and fragile. This is especially common in women after the menopause. Many people with osteoporosis have no symptoms and you may not even know that you have it. However, osteoporosis makes you more likely to have fractures (break bones), especially in your spine, hips and wrists.

How PROTELOS works

PROTELOS, which contains the substance strontium ranelate, belongs to a group of medicines used to treat bone diseases.

PROTELOS works by reducing bone breakdown and stimulating rebuilding of bone and therefore reduces the risk of fracture. The newly formed bone is of normal quality.

2. What you need to know before you take PROTELOS

Do not take PROTELOS:

- if you are allergic to strontium ranelate or any of the other ingredients of PROTELOS (listed in section 6).
- if you have or have had a blood clot (for example, in the blood vessels in your legs or lungs).
- if you are immobilised permanently or for some time such as being wheel-chair bound, or confined to bed or if you are to undergo an operation or recovering from an operation. The risk of vein thrombosis (blood clots in the leg or lungs) may be increased in the event of lengthy immobilisation.
- if you have established ischaemic heart disease, or cerebrovascular disease, e.g. you have been diagnosed with a heart attack, stroke, or transient ischaemic attack (temporary reduction of blood flow to the brain; also known as “mini-stroke”), angina, or blockages of blood vessels to the heart or brain.
- if you have or have had problems with your blood circulation (peripheral arterial disease) or if you have had surgery on the arteries of your legs.
- if you have high blood pressure not controlled by treatment.

Warnings and precautions:

Talk to your doctor or pharmacist before taking PROTELOS:

- if you are at risk of heart disease, this includes high blood pressure, high cholesterol, diabetes, smoking.
- if you are at risk of blood clots.
- if you have severe kidney disease.

Your doctor will evaluate the conditions of your heart and blood vessels regularly, generally every 6 to 12 months for as long you are taking PROTELOS.

During treatment, if you experience an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash), you must immediately stop taking PROTELOS and seek medical advice (see section 4).

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis and severe hypersensitivity reactions (DRESS)) have been reported with the use of PROTELOS.

The highest risk of occurrence of serious skin reactions is within the first weeks of treatment for Stevens-Johnson syndrome and toxic epidermal necrolysis and usually around 3-6 weeks for DRESS. If you develop a rash or serious skin symptoms (see section 4), stop taking PROTELOS, seek urgent advice from a doctor and tell him that you are taking this medicine.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis or DRESS with the use of PROTELOS, you must not be re-started on PROTELOS at any time

If you are of Asian origin, you may be at higher risk of skin reactions.

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 PROTELOS.

Children and adolescents

PROTELOS is not intended for use in children and adolescents (below the age of 18).

Other medicines and PROTELOS:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should stop taking PROTELOS if you have to take oral tetracyclines such as doxycycline or quinolones such as ciprofloxacin (two types of antibiotics). You can take PROTELOS again when you have finished taking these antibiotics. If you are unsure about this ask your doctor or pharmacist. If you are taking medicines containing calcium, you should leave at least 2 hours before you take PROTELOS.

If you take antacids (medicines to relieve heartburn) you should take them at least 2 hours after PROTELOS. If this is not possible, it is acceptable to take the two medicines at the same time.

If you need to have blood or urine tests to check your level of calcium, you should tell the laboratory that you are taking PROTELOS as it may interfere with some testing methods.

PROTELOS with food and drink:

Food, milk and milk products reduce the absorption of strontium ranelate. It is recommended that you take PROTELOS in-between meals, preferably at bedtime at least two hours after food, milk or milk products or calcium supplements.

Pregnancy and breast-feeding:

Do not take PROTELOS during pregnancy or when you are breastfeeding. If you take it by accident during pregnancy or breastfeeding, stop taking it straight away and talk to your doctor.

Driving and using machines:

Protelos is unlikely to affect your ability to drive or use machines.

PROTELOS contains aspartame (E951):

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

3. How to take PROTELOS

The treatment should only be started by a doctor with experience in treating osteoporosis.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

PROTELOS is for oral use.

The recommended dose is one 2 g sachet a day.

It is recommended that you take PROTELOS at bedtime, preferably at least 2 hours after dinner. You may lie down immediately after taking PROTELOS if you wish.

Take the granules contained in the sachets as a suspension in a glass containing a minimum of 30 ml (approximately one third of a standard glass) of water. See instructions below. PROTELOS can interact with milk and milk products, so it is important that you mix PROTELOS only with water to be sure it works properly.



Empty the granules from the sachet into a glass;



Add water;



Stir until the granules are evenly dispersed in the water.

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

Your doctor may advise you to take calcium and vitamin D supplements in addition to PROTELOS. Do not take calcium supplements at bedtime, at the same time as PROTELOS.

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

If you take more PROTELOS than you should:

If you take more sachets of PROTELOS than recommended by your doctor, tell your doctor or pharmacist. They may advise you to drink milk or take antacids to reduce the absorption of the active ingredient.

If you forget to take PROTELOS:

Do not take a double dose to make up for forgotten individual doses. Just carry on with the next dose at the normal time.

If you stop taking PROTELOS:

It is important that you continue taking PROTELOS for as long as your doctor prescribes the medicine. PROTELOS can treat your severe osteoporosis only if you continue to take it.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If the following happens to you, stop using PROTELOS and talk to your doctor immediately:

Common (may affect up to 1 in 10 people):

- Heart attack: sudden crushing pains in your chest which may reach your left arm, jaw, stomach, back and/or shoulders. Other symptoms may be nausea/vomiting, sweating, shortness of breath, palpitations, (extreme) tiredness and/or dizziness. Heart attack may occur commonly in patients at high risk for heart disease. Your doctor will not prescribe PROTELOS for you if you are at particular risk.
- Blood clots in veins: pain, redness, swelling in your leg, sudden chest pain or difficulty breathing.

Rare (may affect up to 1 in 1000 people):

- Signs of severe hypersensitivity reactions (DRESS): initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature (*uncommon*), increased levels of liver enzymes seen in blood tests (*uncommon*) an increase in a type of white blood cell (eosinophilia) (*rare*) and enlarged lymph nodes (*uncommon*).

Very rare (may affect up to 1 in 10,000 people):

- Signs of potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis): initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs may include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

Other possible side effects

Very Common (may affect more than 1 in 10 people):

Itching, hives, skin rash, angioedema (such as swollen face, tongue or throat, difficulty in breathing or swallowing), bone, limb, muscle and/or joint pain, muscle cramps.

Common:

Vomiting, abdominal pain, reflux, indigestion, constipation, flatulence, difficulty in sleeping, inflammation of the liver (hepatitis), swelling in limbs, bronchial hyperreactivity (symptoms include wheezing and shortness of breath and cough), increased level of a muscle enzyme (Creatine phosphokinase), increased levels of cholesterol.

Nausea, diarrhoea, headache, eczema, memory trouble, fainting fit, pins and needles, dizziness, vertigo. However, these effects were mild and short-lived and usually did not cause the patients to stop taking their treatment. Talk to your doctor if any effects become troublesome or persist.

Uncommon (may affect up to 1 in 100 people):

Seizures, oral irritation (such as mouth ulcers and gum inflammation), hair loss, feeling confused, feeling unwell, dry mouth, skin irritation.

Rare:

Reduction in production of blood cells in the bone marrow.

If you have stopped treatment due to hypersensitivity reactions, do not take PROTELOS again.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PROTELOS

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and the sachet after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Once reconstituted in water, the suspension is stable for 24 hours. However, it is recommended to drink the suspension immediately after preparation (see section 3).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What PROTELOS contains

- The active substance is strontium ranelate. Each sachet contains 2 g of strontium ranelate.
- The other ingredients are aspartame (E 951), maltodextrin, mannitol (E 421).

What PROTELOS looks like and contents of the pack

PROTELOS is available in sachets containing yellow granules for oral suspension. PROTELOS is supplied in boxes of 7, 14, 28, 56, 84 or 100 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Les Laboratoires Servier
50, rue Carnot
92284 Suresnes cedex
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Manufacturer(s)

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>