PROTAXOS 2 g granules for oral suspension

Strontium ranelate

In this leaflet:

What PROTAXOS is and what it is used for

PROTAXOS is a non-hormonal medicine used to treat osteoporosis:

- in postmenopausal women to reduce 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 PROTAXOS works

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

PROTAXOS 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.

Before you take PROTAXOS

Do not take PROTAXOS:

- if you are allergic to strontium ranelate or any of the other ingredients of PROTAXOS (listed in section 'Contents of the pack and other information').
- 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.

Warnings and precautions:

Talk to your doctor or pharmacist before taking PROTAXOS:

- if you have severe kidney disease.

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 PROTAXOS and seek medical advice.

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

Stevens-Johnson syndrome and toxic epidermal necrolysis appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for 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.

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

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

If you develop a rash or these skin symptoms, stop taking PROTAXOS, seek urgent advice from a doctor and tell him that you are taking this medicine.

If you are of Asian origin, talk to your doctor before taking PROTAXOS as you may be at higher risk of skin reactions.

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

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

- You should stop taking PROTAXOS if you have to take oral tetracyclines or quinolones (two types of antibiotics). You can take PROTAXOS 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 PROTAXOS.
- If you take antacids (medicines to relieve heartburn) you should take them at least 2 hours after PROTAXOS. If this is not possible, it is acceptable to take the two medicines at the same time.

How to take PROTAXOS

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

PROTAXOS is for oral use.
The recommended dose is one 2g sachet a day.

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

Take the granules contained in the sachets as a suspension in a glass of water (see instructions below).

PROTAXOS can interact with milk and milk products, so it is important that you mix PROTAXOS 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 it 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 PROTAXOS. Do not take calcium supplements at bedtime, at the same time as PROTAXOS.

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

If you take more PROTAXOS than you should
If you take too many sachets of PROTAXOS, 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 PROTAXOS
Do not take a double dose to make up for forgotten individual doses. Just carry on with the next dose at the normal time.

While taking PROTAXOS

PROTAXOS with food and drink:
Food, milk and milk products reduce the absorption of strontium ranelate. It is recommended that you take PROTAXOS 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 PROTAXOS 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:
PROTAXOS is unlikely to affect your ability to drive or use machines.

PROTAXOS 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.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The frequency of possible side effects listed below is defined using the following convention:
very common: may affect more than 1 in 10 people
common: may affect up to 1 in 10 people

uncommon: may affect up to 1 in 100 people
rare: may affect up to 1 in 1,000 people
very rare: may affect up to 1 in 10,000 people
not known: frequency cannot be estimated from the available data

Common:
Blood clots. Signs of a blood clot include painful swelling in your leg, sudden chest pain or difficulty breathing. See a doctor straight away if you experience any of these symptoms.
Nausea, diarrhoea, headache, skin irritation, memory troubles, fainting fit. 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:
Seizures.

Rare:
Severe hypersensitivity reactions (DRESS: see section 'Before you take PROTAXOS')

Very rare:
Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 'Before you take PROTAXOS').

Not known:
Vomiting, abdominal pain, reflux, indigestion, constipation, flatulence, dry mouth, pins and needles, dizziness, vertigo, difficulty in sleeping, inflammation of the liver (hepatitis)**,** oral irritation (such as mouth ulcers and gum inflammation), bone, muscle and/or joint pain, muscle cramps, hair loss, reduction in production of blood cells in the bone marrow, itching, hives, blistering, angioedema (such as swollen face, tongue or throat, difficulty in breathing or swallowing), swelling in limbs, feeling unwell, feeling confused, bronchial hyperreactivity (symptoms include wheezing, shortness of breath and cough).
If you have stopped treatment due to hypersensitivity reactions, do not take PROTAXOS again If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

After taking PROTAXOS

How to store PROTAXOS

Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

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

Disposal

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.

Product Description

What PROTAXOS 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 PROTAXOS looks like and contents of the pack

PROTAXOS is available in sachets containing yellow granules for oral suspension**.** PROTAXOS is supplied in a box of 28 sachets.

Registration number

MAL20071622A

Manufacturer

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Product Licence Holder

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