**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**PROTELOS 2 g granules for oral suspension**
Strontium ranelate

**Read all of this leaflet carefully before you start taking this medicine.**
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

**In this leaflet:**


## 1. WHAT PROTELOS IS AND WHAT IT IS USED FOR

PROTELOS is a non-hormonal medicine used to treat osteoporosis in postmenopausal women. PROTELOS 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. BEFORE YOU TAKE PROTELOS

**Do not take PROTELOS:**
- if you are allergic (hypersensitive) to strontium ranelate or any of the other ingredients of PROTELOS.

**Take special care with PROTELOS:**
Before taking PROTELOS talk to your doctor :
- if you have severe kidney disease.
- 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. The risk of vein thrombosis (blood clots in the leg) may be increased in the event of lengthy immobilisation.
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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. If you have stopped treatment due to hypersensitivity reactions it should be permanent and you should not re-start therapy with PROTELOS.

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

**Taking other medicines:**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

-You should stop taking PROTELOS if you have to take oral tetracyclines or quinolones (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.

**Taking 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:**
PROTELOS is meant for use only in postmenopausal women. Therefore, 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.

**Important information about some of the ingredients of PROTELOS:**
PROTELOS 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.

## 3. HOW TO TAKE PROTELOS

Always take PROTELOS exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

PROTELOS is for oral use.
The recommended dose is one 2g 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 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 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 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 too many sachets of PROTELOS, 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.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, PROTELOS 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 (affects more than 1 user in 10)
common (affects 1 to 10 users in 100)
uncommon (affects 1 to 10 users in 1,000)
rare (affects 1 to 10 users in 10,000)
very rare (affects less than 1 user in 10,000)
not known (frequency cannot be estimated from the available data)

*Common:*
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:*
Blood clots, seizures.

*Not known:*
Vomiting, abdominal pain, 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, hypersensitivity syndromes (allergic reactions including rash, a high temperature, increased levels of

liver enzymes seen in blood tests and increase in a type of white blood cell (eosinophilia), enlarged lymph nodes), itching, hives, blistering, angioedema (such as swollen face, tongue or throat, difficulty in breathing or swallowing), swelling in limbs, feeling confused, bronchial hyperreactivity (symptoms include wheezing and shortness of breath).
In some cases very serious hypersensitivity reactions have been reported. Therefore you should immediately stop taking PROTELOS and see your doctor if you experience symptoms of angioedema or hypersensitivity syndrome.
If you have stopped treatment due to hypersensitivity syndrome, it should be permanent and you should not re-start therapy with PROTELOS.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE PROTELOS

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use after the expiry date which is stated on the box and the sachet after EXP.
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)

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER 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**

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