

PATIENT ALERT CARD

PROTELOS[®]

Dear patient,

You have been prescribed **Protelos[®] (strontium ranelate)** by your doctor, for the treatment of severe osteoporosis.

This patient card contains **important safety information** on possible side effects that you need to be aware of before and during treatment with Protelos[®].

- Please show this card to any doctor or nurse involved in your treatment and ask him/her to fill in the back.
- Please read the Package Information Leaflet which is included in each Protelos[®] pack for more information.

If you experience any of these side effects, please consult your doctor immediately.

Doctor's name:

Doctor's phone number:

Name of the patient:

What you need to know before you take Protelos[®]

Protelos[®] may increase cardiovascular, vein thrombosis, and allergic reaction risks

You must not take Protelos[®]:

- If you have been diagnosed with a heart attack or angina (blockages of blood vessels to the heart), or stroke (blockages of blood vessels to the brain) or transient ischemic attack (mini-stroke).
- If you have or have had problems with your blood circulation in your legs (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.
- If you have or have had a blood clot (eg, in the blood vessels of your legs or lungs).
- If you are immobilized permanently or for some time such as being wheel-chair bound, or confined to bed, or if you are to undergo an operation or are recovering from an operation. The risk of vein thrombosis may be increased in the event of lengthy immobilization.
- If you are allergic to strontium ranelate or any of the other ingredients of Protelos[®].

During Protelos[®] treatment, seek for medical advice immediately if you have any of the following symptoms:

- Sudden crushing pains in your chest that may reach your left arm, jaw, stomach, back, and/or shoulders as these can be related to a heart attack. Others symptoms may include nausea/vomiting, sweating, shortness of breath, palpitations, (extreme) tiredness, and/or dizziness.
- Painful swelling in your leg, sudden chest pain, or difficulty breathing because these can be related to blood clots in your legs or in your lungs.
- Any allergic reaction such as swelling of the face, tongue, or throat, difficulty in breathing or swallowing, skin rash (eg, reddish target-like spots or circular patches often with central blisters on the trunk, or flu-like symptoms and a rash on the face).

You must immediately stop taking Protelos[®].

Talk to your doctor or pharmacist:

- If you are at risk of heart disease, this includes high blood pressure, high cholesterol, diabetes, and/or smoking.
Heart attack may occur commonly in patients at high risk for heart disease.
- If you are at risk of blood clots.

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 the leaflet. You can also report side effects directly via

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

203 Level 3, Rue D'Argens

GŻR-1368 Gzira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

By reporting side effects you can help provide more information on the safety of this medicine.

Your doctor will give you a **regular 6 to 12 months** check-up of your heart and blood vessels for as long as you are taking Protelos[®].

Starting date of treatment:

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Follow-up visit:

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