PROTELOS®

PRESCRIBER GUIDE AND CHECKLIST

(strontium ranelate)

This guide is part of the Risk Management Plan of Protelos®

It is intended to inform you regarding the use and the safety profile of Protelos®.

This guide provides you with information and recommendations regarding appropriate and safe use of Protelos® (strontium ranelate) in patients with severe osteoporosis and includes:

- Protelos® overview.
- Updated therapeutic indication.
- Recommendations for the initiation of Protelos® treatment.
- Contraindications.
- Recommendations in patients with cardiovascular, venous thromboembolic and skin reactions risks.
- Monitoring of cardiovascular risks.
- Counseling your patient.

Protelos®

Protelos® is a treatment for osteoporosis which was granted a European Marketing Authorization in September 2004. Protelos® is currently registered in over 100 countries.

• Protelos® is a synthesized drug composed of 2 atoms of stable strontium and an organic moiety, ranelic acid. *In vitro*, the active substance, strontium ranelate, acts by rebalancing bone turnover in favor of bone formation.

• The recommended daily dose is one 2 g sachet taken orally as a single administration.

Therapeutic indications

Treatment of severe osteoporosis:

- in postmenopausal women,
- in adult men,

at high risk for fracture for whom treatment with other medicinal products approved for the treatment of osteoporosis is not possible due to, for example,

contraindications or intolerance. In postmenopausal women, Protelos® reduces the risk of vertebral and hip fractures.

The decision to prescribe Protelos® should be based on an assessment of the individual patient's overall risks.

Before prescribing Protelos®

Protelos® is only indicated in patients with severe osteoporosis who are intolerant of other alternative treatments or for whom these are contraindicated.

Treatment should only be initiated by a physician with experience in the treatment of osteoporosis.

Assessment of the individual patient overall's risk

Each decision to start Protelos® should be based on an assessment of the individual patient's overall risk with a fully informed patient and treatment should be re-evaluated every 6 to 12 months especially with regards to any changes in the patient's cardiovascular risks.

The Protelos® Patient Alert Card should be given to each patient.

Protelos® is contraindicated and must not be used in patients with:

- Established, current or past history of ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
- Uncontrolled hypertension.
- Current or previous venous thromboembolic events (VTE), including deep vein thrombosis and pulmonary embolism.
- Temporary or permanent immobilisation due to e.g. post-surgical recovery or prolonged bed rest.
- Hypersensitivity to the active substance (strontium ranelate) or any of the excipients (refer to SmPC for a full list of excipients)

Special warnings and precautions for use:

- Patients with significant risk factors for cardiovascular events such as hypertension, hyperlipidaemia, diabetes mellitus, or smoking, should only be treated with Protelos® after careful consideration.

- Protelos should be used with caution in patients at risk of VTE.
    - When treating patients over 80 years at risk of VTE, the need for continued treatment with Protelos® should be re-evaluated.

- As soon as possible in the event of an illness or a condition leading to immobilization, the treatment should be discontinued and adequate preventive measures taken.

- If symptoms or signs of Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) (e.g. progressive skin rash often with blisters or mucosal lesions) or Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) (e.g. rash, fever, eosinophilia and systemic involvement, (e.g. adenopathy, hepatitis, interstitial nephropathy, interstitial lung disease)) are present, Protelos® treatment should be discontinued immediately and not re-started at any time.

Monitoring of cardiovascular risks

- Before starting treatment, patients should be evaluated with respect to cardiovascular risk.
- During Protelos® treatment, cardiovascular risks should be monitored on a regular basis generally every 6 to 12 months.
- Treatment should be stopped if the patient develops ischaemic heart disease, peripheral arterial disease, cerebrovascular disease or if hypertension is uncontrolled.

Counselling your patient

As part of discussions with your patients or their care givers, please ensure that:

- You provide a full description of the cardiovascular, venous thromboembolic and skin reaction risks of Protelos®
- You instruct the patient to read the Patient Information Leaflet
- Your patient will be given a patient alert card that he/she needs to read and keep during the course of the treatment, and to show to any doctor involved in the treatment.

Please advise patient that, if symptoms of myocardial infarction, VTE or Skin reactions occur during treatment, they should stop taking Protelos® and seek medical advice immediately.

For your patients being currently treated with Protelos®

You must inform each of your patients currently receiving Protelos® of the product's risk information including Myocardial Infarction, VTE and skin reactions associated with the use of Protelos®.

Further information on Protelos®

For further information on Protelos®, please read the Summary of Product Characteristics here attached that is also available on Website: www.hpra.ie Health Products Regulatory Authority website.

For further inquiries concerning this information, please contact the Medical Information Department of SERVIER Laboratories Ireland 01-6638110 and Medical and Regulatory Affairs Manager, Servier Laboratories, Block 2, West Pier Business Campus, Old Dunleary Road, Dun Laoghaire, Co. Dublin

You will find on the back of this page a checklist to assist you when prescribing Protelos®.