PRESCRIBER CHECKLIST

(strontium ranelate)

THE FOLLOWING ARE CONTRAINDICATIONS FOR USE OF PROTELOS ®

If your patient is concerned by any of the criteria below, DO NOT PRESCRIBE PROTELOS®

• Established, current, or past history of **ischemic 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 immobilization** due to e.g., postsurgical recovery or prolonged bed rest.

• Hypersensitivity to strontium ranelate or to any of the excipients.

THE FOLLOWING INFORMATION IS DERIVED FROM WARNINGS AND PRECAUTIONS

• Patients with significant risk factors for cardiovascular events (e.g., hypertension, hyperlipidemia, diabetes mellitus, smoking) should only be treated with Protelos® after careful consideration. **During the treatment, cardiovascular risks should be monitored on a regular basis, generally every 6 to 12 months.**

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

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