Important information – Do not discard!

▼ Strontium ranelate Aristo

Important Risk Minimisation Information for Healthcare Providers

PRESCRIBER GUIDE AND CHECKLIST

This information is non-promotional and should be read carefully before prescribing Strontium ranelate Aristo. Following is important information on minimising cardiovascular risks, venous thromboembolism and skin reactions with strontium ranelate.

This information does not replace the Summary of Product Characteristics (SmPC) which should be read and understood in full before initiating therapy.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions (see the page 3 for details on how to report).

This guide provides you with information and recommendations for the appropriate use of strontium ranelate

- Therapeutic indications.
- Before prescribing strontium ranelate.
- Contraindications.
- Special warnings and recommendations for use.
- Monitoring of cardiovascular risks.
- Counselling your patient.

THERAPEUTIC INDICATIONS OF STRONTIUM RANELATE

Treatment of severe osteoporosis:

- in postmenopausal women,
- in adult men,

at high risk of 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, strontium ranelate reduces the risk of vertebral and hip fractures.

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

BEFORE PRESCRIBING STRONTIUM RANELATE

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

Assessment of the individual patient's overall risk

The decision to initiate strontium ranelate should be based on an assessment of the individual patient's overall risk. The patient should be fully informed of these risks and treatment should be re-evaluated every 6 to 12 months especially with regards to any changes in the patient's cardiovascular risks.

The strontium ranelate Patient Alert Card should be given to each patient.

CONTRAINDICATIONS

Strontium ranelate should not be used in patients with:

- Current or previous 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 (e.g. post-surgical recovery or prolonged bed rest).
- Hypersensitivity to the active substance (strontium ranelate) or to any of the excipients (refer to SmPC for a full list of excipients)

Warnings and recommendations:

- Patients with significant risk factors for cardiovascular events such as hypertension, hyperlipidaemia, diabetes mellitus, or smoking, should only be treated with strontium ranelate after careful consideration.
- Strontium ranelate should be used with caution in patients at risk of VTE.
- The need for continued treatment with strontium ranelate should be re-evaluated in patients over 80 years who have been diagnosed at risk of VTE.
- Strontium ranelate should be discontinued as soon as possible in the event of an illness or a condition leading to immobilisation and adequate preventive measures taken. Therapy should not be restarted until the initiating condition has resolved and the patient is fully mobile. If VTE occurs, strontium ranelate should be stopped.
- 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) (e.g. rash, fever, eosinophilia and systemic involvement, (e.g. adenopathy, hepatitis, interstitial nephropathy, interstitial lung disease)) are present, strontium ranelate treatment should be discontinued immediately and not re-started at any time.
  Patients should be advised of the signs and symptoms and monitored closely for skin reactions. The highest risk for occurrence of SJS or TEN is within the first weeks of treatment and usually around 3-6 weeks for DRESS.
- Strontium ranelate is not recommended in patients with a creatinine clearance below 30ml/min.

Monitoring of cardiovascular risks

- Before starting treatment, patients should be evaluated with respect to cardiovascular risk.
- Cardiovascular risks should be monitored 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 about strontium ranelate

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

- You provide a full explanation of the potential cardiovascular, venous thromboembolic and skin reaction risks of strontium ranelate,
- You instruct the patient to read the Package Information Leaflet carefully,
- Your patient is given a Patient Alert Card that he/she needs to read and keep during the course of their treatment, and this is shown to any doctor or nurse involved in their treatment.

Please advise your patient that, if symptoms of myocardial infarction, VTE or severe skin reactions occur during treatment, they should stop taking strontium ranelate and seek urgent medical advice.

Please also ensure that you provide this counselling to patients who are currently being prescribed strontium ranelate.

Further information on strontium ranelate

For further information on strontium ranelate, please read the Summary of Product Characteristics.

Call for reporting
Please report any suspected adverse reactions through the Yellow Card Scheme. The easiest way to report is online at www.mhra.gov.uk/yellowcard. Alternatively, complete a paper Yellow Card form which you can post to FREEPOST YELLOW CARD. Yellow Cards can be found in the BNF, MIMS or ordered by calling the Yellow Card Information Service freephone on 0800 731 6789.

Suspected adverse reactions may also be reported to Aristo Pharma Limited:

Email: medinfo@aristo-pharma.co.uk
Tel: 01483 406 911

Company contact point
For further inquiries concerning this information, please contact the Medical Information Department of Aristo Pharma in the UK
Telephone: 01483 406 911
Email: medinfo@aristo-pharma.co.uk

Aristo Pharma Limited
The North Suite, Avro House, 49 Lancaster Way Business Park, Ely, Cambridgeshire, CB6 3NW.

Please also refer to the strontium ranelate Prescriber Checklist on page 4 to assist you when prescribing strontium ranelate.

ARISTO

Strontium ranelate Aristo

CONTRAINDICATIONS

Strontium ranelate should not be used in patients with:

- Current or previous **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** (e.g. post-surgical recovery or prolonged bed rest).
- Hypersensitivity to strontium ranelate or to any of the excipients.

WARNINGS AND RECOMMENDATIONS

- Patients with significant risk factors for cardiovascular events such as hypertension, hyperlipidaemia, diabetes mellitus, or smoking, should only be treated with strontium ranelate after careful consideration.
- **Cardiovascular risk should be monitored 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.
- Strontium ranelate should be used with caution in patients at risk of VTE.
- The need for continued treatment with strontium ranelate should be re-evaluated in patients over 80 years who have been diagnosed at risk of VTE.
- Strontium ranelate should be discontinued as soon as possible in the event of an illness or a condition leading to immobilisation and adequate preventive measures taken. Therapy should not be restarted until the initiating condition has resolved and the patient is fully mobile. If VTE occurs, strontium ranelate should be stopped.
- 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) (e.g. rash, fever, eosinophilia and systemic involvement, (e.g. adenopathy, hepatitis, interstitial nephropathy, interstitial lung disease)) are present, strontium ranelate treatment should be discontinued immediately and not re-started at any time.
  Patients should be advised of the signs and symptoms and monitored closely for skin reactions. The highest risk for occurrence of SJS or TEN is within the first weeks of treatment and usually around 3-6 weeks for DRESS.
- Strontium ranelate is not recommended in patients with a creatinine clearance below 30ml/min.