Direct Healthcare Professional Communication – New contraindications for strontium ranelate (Protelos)

Dear Healthcare Professional,

This letter is to inform you of new contraindications for strontium ranelate (Protelos) and is sent in agreement with the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

Summary:

Protelos is now contraindicated in patients with:
- 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.

Further information on the safety concern

Protelos (strontium ranelate) is authorised for the treatment of osteoporosis in postmenopausal women to reduce the risk of vertebral and hip fractures.

A European review was initiated following publication of a study in France¹ where 199 severe adverse reactions, 52% cardiovascular events (mostly VTE events) and 26% cutaneous events were described. The risk of VTE in patients taking strontium ranelate has been known since authorisation. The CHMP (the EMA’s Committee on Medicinal Products for Human Use) has reviewed all data available from clinical trials, epidemiological studies and post-marketing setting on VTE. In order to minimise the risk of VTE, the CHMP concluded that the product information should be strengthened by including new contraindications, as detailed above. Furthermore, the warnings were updated to recommend caution when prescribing strontium ranelate to patients over 80 years at risk of VTE.

¹ Ranélate de strontium (Protelos): effets indésirables rapporté en France; Presse Med. 2011; 40(10):e453-e462. [Adverse drug reactions of strontium ranelate (Protelos) in France; study period Jan 2006 to Mar 2009, estimated number of patients exposed 301,951]
The review also considered the risk of hypersensitivity reactions, such as drug rash with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). Serious cutaneous reactions have been reported by health care professionals. The warnings were updated to advise prescribers to be alert regarding the time to event and the signs and symptoms of these cutaneous reactions.

**Call for reporting**
Please report any suspected adverse reactions through the Yellow Card Scheme. The easiest way is to report is online at [www.mhra.gov.uk/yellowcard](http://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, ABPI Compendium or ordered by calling the Yellow Card Information Service freephone on 0800 731 6789.

Suspected adverse reactions should also be reported to Servier Laboratories Ltd Medical Information using the contact details in **Communication information** below.

**Communication information**
For further inquiries concerning this information, please contact the Medical Information Department of SERVIER in the UK

Tel: 01753 666409

Email: [Medical.Information@uk.netgrs.com](mailto:Medical.Information@uk.netgrs.com)

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Yours faithfully

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Chief Executive Officer