SERVIER LABORATORIES (IRELAND) LTD. Reg. in Ireland No. 46172
Block 2, West Pier Business Campus, Old Dunleary Road, Dún Laoghaire, Co. Dublin.
Tel: (01) 663 8110
Fax: (01) 663 8120

Date: 04/04/2012

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

Dear Healthcare Professional,

This letter is to inform you on new contraindications for strontium ranelate (Protelos/Osseor) and is sent in agreement with the European Medicines Agency (EMA) and Irish Medicines Board (IMB).

Summary:

Protelos/Osseor 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/Osseor (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 France[1] 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.

The review considered also 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.

[1] Ranélate de strontium (Protelos): effets indésirables rapporté en France; Presse Med. 2011; 40(10):e453-e462.

Call for reporting
As a reminder, there is a need to report any suspected adverse reactions in accordance with the national spontaneous reporting system to www.imb.ie.

Communication information
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

Yours sincerely,

Mr Yann Mazemann
General Manager