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Direct Healthcare Professional Communication on cases of hypersensitivity syndromes in post menopausal women treated with strontium ranelate (▼Protelos)

Dear Healthcare Professional,

Within 3 years of marketing there have been 16 reported cases, including two with a fatal outcome, of the hypersensitivity syndrome known as DRESS (Drug Rash with Eosinophilia and Systemic Symptoms) syndrome associated with use of Protelos. This should be seen in the context of a total exposure of approximately 570,000 patient years. This life-threatening syndrome is characterised by the presence of skin reactions, fever, eosinophilia, adenopathy and systemic involvement e.g. hepatitis, interstitial nephropathy, interstitial lung disease. Time to onset was usually around 3-6 weeks after initiating therapy and in most cases the reaction resolved upon discontinuation of Protelos and initiation of corticosteroid therapy. However recovery may be slow and recurrences of the syndrome have been reported after discontinuation of corticosteroid therapy. The underlying mechanism is not known.

Patients should be told to stop Protelos immediately and permanently when a rash occurs and to seek medical advice. Patients who have stopped treatment due to hypersensitivity reactions should not re-start therapy with Protelos.

This information should be taken into account when treating patients with Protelos, and treatment should be discontinued immediately and permanently if a skin reaction occurs.

The SPC and the PIL has been updated accordingly in a rapid procedure under the sections 4.4 "special warnings and precautions for use" and 4.8 "undesirable side effects". The revised text is appended to this letter, with the relevant sections boxed and shaded

Please report any suspected adverse reactions through the Yellow Card Scheme (www.yellowcard.gov.uk).

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

Tel: 0800 9807216

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Yours faithfully

Dr Frédéric Girard
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