Strontium still authorised despite an unfavourable opinion of the European pharmacovigilance committee

In early 2014 the indications of strontium ranelate were further restricted in the European Union, and the French pharmacoeconomic committee has finally judged strontium ranelate to have "insufficient medical benefit".

Strontium ranelate (Protelos® - Servier), a drug authorised in the European Union for severe osteoporosis, has at best only modest efficacy in secondary prevention of vertebral fractures (1). In stark contrast, it carries a risk of disproportionate adverse effects, including myocardial infarction, embolism, vein thrombosis, hypersensitivity reactions (including Lyell’s syndrome and Dress [drug reaction with eosinophilia and systemic symptoms]), impaired consciousness, seizures, hepatitis and cytopenia (1-4). Ocular disorders (loss of visual acuity and inflammation) have also been reported (5).

In early 2014, as part of a European reassessment, the European Pharmacovigilance Risk Assessment Committee (PRAC) recommended suspending marketing authorisation for products containing strontium ranelate in the European Union (a)(1).

The European Committee for Medicinal Products for Human Use (CHMP) considered that "the cardiovascular risk in patients taking Protelos can be managed by restricting its use to patients with no history of heart and circulatory problems (...). In addition, patients (...) should be screened and monitored regularly, every 6 to 12 months" (6,7). Ten Member States, including France, disagreed with this conclusion (7).

In April 2014, the European Commission approved the CHMP recommendation and allowed strontium ranelate to remain on the market (8). This decision is binding on all EU Member States. The French health products agency (ANSM) which had advised against starting treatment with strontium ranelate pending the European Commission’s decision, had to inform healthcare professionals of the new instructions for strontium ranelate, which notably include last-resort use only, and regular cardiovascular monitoring (1,7). In July, the French pharmacoeconomic committee considered that strontium ranelate still had “insufficient medical benefit” under these new conditions (9). Once again, the CHMP, followed by the European Commission, favours drug companies over patients’ health. In practice, it is best to follow the advice of PRAC: this drug should have been discarded long ago.

Selected references from Prescrire’s literature search.

4- EMA “Protelos and Osseeor. Strontium ranelate. CHMP scientific conclusions and PRAC assessment report of the review under article 20 of regulation (EC) n° 726/2004” 28 February 2014: 29 pages.
5- EMA “PRAC minutes of the meeting on 2-5 December 2013” 9 January 2014: 58 pages.
6- EMA “European medicines agency recommends that Protelos/Osseor remain available but with further restrictions” 21 February 2014: 3 pages.
7- ANSM “Point d’information - Le CHMP recommande le maintien sur le marché de Protelos (ranélate de strontium) en restreignant de nouveau ses indications” 27 February 2014 + “Lettre aux professionnels de santé - Protelos (...) nouvelles restrictions d’indication” 24 March 2014: 5 pages.
10- EMA “Questions and answers. Withdrawal of the applications for a change to the marketing authorisation of Protelos” 23 May 2014: 2 pages.
11- EMA “Questions and answers. Withdrawal of the marketing authorisation applications for Dietelos and Issalos” 25 April 2014: 2 pages.

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