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Public statement

Osseor

Withdrawal of the marketing authorisation in the European Union

On 14 April 2020, the European Commission withdrew the marketing authorisation for Osseor (strontium ranelate) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Les Laboratoires Servier, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Osseor was granted marketing authorisation in the EU on 21 September 2004 for treatment of osteoporosis. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2009. It was then granted unlimited validity in 2014. The product had not been marketed in the EU since 2017.

The European Public Assessment Report (EPAR) for Osseor will be updated to indicate that the marketing authorisation is no longer valid.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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