European Medicines Agency
Press office

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PRESS RELEASE
EMEA recommends changes in the product information for Protelos/Osseor due to the risk of severe hypersensitivity reactions

The European Medicines Agency (EMEA) agrees on the inclusion of warnings concerning the risk of severe hypersensitivity reactions in the prescribing and patient information for Protelos/Osseor, as an urgent measure. These products, which contain strontium ranelate, were approved in the European Union in September 2004 for the treatment of postmenopausal osteoporosis to reduce the risk of vertebral and hip fractures.

Up to now, 16 cases of 'drug rash with eosinophilia and systemic symptoms (DRESS)' in patients treated with Protelos/Osseor, two of which were fatal, have been reported to the EMEA, following a total of around 570,000 patient-years of worldwide exposure. DRESS is a serious and life-threatening condition. The reported serious reactions started within 3 to 6 weeks of the initiation of the treatment, with skin rash, accompanied by a fever, swollen glands, increased numbers of white cells in the blood and effects on the liver, kidneys and lung.

Having assessed the newly available data, the Agency's Committee for Medicinal Products for Human Use (CHMP) has agreed that the product information be provisionally updated in a rapid procedure to include warnings on severe hypersensitivity syndromes, including DRESS and Stevens Johnson-Syndrome, in the prescribing and patient information, as an urgent measure.

Patients are advised to stop treatment with Protelos/Osseor when a rash occurs and to seek medical advice. Once the treatment has been stopped, Protelos/Osseor should not be re-introduced.

As for all medicinal products marketed in the European Union, the CHMP will continue to monitor Protelos/Osseor, and take appropriate actions if further concerns arise.

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Notes:
1. The European Public Assessment Report (EPAR) for Protelos/Osseor can be found here.
2. The revised product information can be found here.
3. A separate question-and-answer document can be found here.
4. These changes to the product information have been provisionally introduced via an 'urgent safety restriction' procedure. These changes will be formally endorsed by the CHMP via a scientific opinion at the December plenary meeting.
5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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