IRISH MEDICINES BOARD

Notice Information: - 3rd Party Publications 26 April 2013

Part 1. Product Information

a)	Title:	European Medicines Agency (EMA) announces recommendation to restrict the use of Protelos/Osseor (strontium ranelate)
b)	Product Name/Type:	Protelos/Osseor
c)	Active Substance:	Strontium ranelate

Part 2. Problem/Issue

a) Problem/Issue:

The EMA's Committee for Medicinal Products for Human Use (CHMP) has recommended a restriction in the use of the osteoporosis medicine Protelos/Osseor, following an assessment of data showing an increased risk of serious heart problems. The CHMP recommended that Protelos/Osseor should only be used to treat severe osteoporosis in postmenopausal women at high risk of fracture and severe osteoporosis in men at increased risk of fracture. Additional measures, including restrictions in patients with heart or circulatory problems, were also recommended to minimise the heart risks of these medicines.

The CHMP recommendation is based on the advice of the Pharmacovigilance Risk Assessment Committee (PRAC), which evaluated Protelos/Osseor as part of a routine benefit-risk assessment. During the assessment, data from clinical studies in post-menopausal women were evaluated, showing a higher risk of heart attack with Protelos/Osseor than with placebo, with no observed increase in mortality risk. Given the other serious risks (blood clots and rare serious skin reactions) previously identified with the medicine, the PRAC concluded that certain restrictions in the use of the medicine should be in place for the benefit-risk balance to remain favourable and that a further in-depth evaluation of the benefits and risks of the medicine was needed.

The CHMP agreed with the PRAC 's recommendations and this opinion will be sent to the European Commission for a legally binding decision. A further wide-ranging evaluation of the benefits and risks of Protelos/Osseor will now be conducted by PRAC and CHMP . In the meantime, the current recommendations are intended to minimise the risk of serious heart problems.

Part 3. Enquiries

a)	All enquiries should be made to:	For full EMA statement please refer to link below: European Medicines Agency announces recommendation to restrict the use of Protelos/Osseor (strontium ranelate)