EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2012
EMA/CHMP/553672/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Picato

ingenol mebutate

On 20 September 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Picato, 150 micrograms/g, 500 micrograms/g gel intended for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults. The applicant for this medicinal product is LEO Pharma A/S. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Picato is ingenol mebutate, an antibiotic and chemotherapeutic for dermatological use (D06BX02) that causes induction of local lesion cell death and promotes an inflammatory response characterised by infiltration of immunocompetent cells.

The benefits with Picato are its ability to improve the complete response rate of actinic keratosis lesions. The most common side effects are local skin responses including erythema, flaking/scaling, crusting, swelling, vesiculation/pustulation and erosion/ulceration at the application site of Picato.

A pharmacovigilance plan for Picato will be implemented as part of the marketing authorisation.

The approved indication is: "Picato is indicated for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Picato and therefore recommends the granting of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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