21 June 2012
EMA/CHMP/423167/2012
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Zyclara

Imiquimod

On 21 June 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 Zyclara, 3.75 %, cream intended for the topical treatment of clinically typical, visible or palpable actinic keratoses (AK) of the full face or balding scalp in adults when other topical treatment options are contraindicated or less appropriate. The applicant for this medicinal product is Meda AB. 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 Zyclara is imiquimod, an antiviral, (D06BB10). Imiquimod is an immune response modifier. It is the lead compound of the imidazoline family. Imiquimod induces the release of interferon alpha (IFN-α) and other cytokines from a variety of human and animal cells (e.g. from human monocytes/macrophages and keratinocytes).

Zyclara is a hybrid of Aldara, which has been authorised in the EU since 18 September 1998. Studies have demonstrated the satisfactory quality of Zyclara. Zyclara differs from Aldara in therapeutic indication and strength; therefore bioequivalence cannot be demonstrated through bioavailability studies and new clinical studies have been carried out.

The benefits with Zyclara are that it has lower concentration of active substance than Aldara allowing the treatment of areas larger than 25 cm2 and a higher number of lesions. The most common side effects are local skin reactions (most frequently erythema, scab, and exfoliation/application site dryness) at the application site. Some systemic adverse reactions, including headache, fatigue, were also reported.

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

The approved indication is: "Zyclara is indicated for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate". It is proposed that Zyclara is prescribed by physicians experienced in the treatment of actinic keratoses.

[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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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 will be 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 Zyclara and therefore recommends the granting of the marketing authorisation.