15 December 2016
EMA/764254/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ledaga

chlormethine

On 15 December 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ledaga, intended for the treatment of mycosis fungoides-type cutaneous T-cell lymphoma. Ledaga was designated as an orphan medicinal product on 22 May 2012. The applicant for this medicinal product is Actelion Registration Ltd.

Ledaga will be available as a 160 µg/g gel. The active substance of Ledage is the antineoplastic chlormethine (ATC code: L01AA05), a bifunctional alkylating agent that inhibits rapidly proliferating cells.

The benefits with Ledaga are its ability to treat cutaneous T cell lymphoma lesions leading to resolution of skin patches, plaques and tumours. The most common side effects are related to skin adverse reactions such as dermatitis, pruritis, skin infections, skin ulceration and blistering, and skin hyperpigmentation.

Ledaga is a hybrid medicine[2] of Caryolysine which has been authorised in the EU since 1946. Ledaga contains the same active substance as Caryolysine, but will be available as a gel for cutaneous use.

Studies have demonstrated the satisfactory quality of Ledaga. Since Ledaga is administered as a topical agent resulting in no systemic exposure, a bioequivalence study versus the reference product Caryolysine was not required.

The full indication is: "Ledaga is indicated for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL) in adult patients (see section 5.1)."

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.

[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
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact