19 November 2015
EMA/765144/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Episalvan

birch bark extract

On 19 November 2015 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Episalvan, intended for the treatment of partial thickness wounds in adults. The applicant for this medicinal product is Birken AG.

Episalvan will be available as a gel for cutaneous use. The active substance of Episalvan is birch bark extract (as dry extract, refined) from *Betula pendula* Roth/*Betula pubescens* Ehrh., corresponding to 72-88 mg betulin. It is thought to work by modulating several pro-inflammatory mediators in the first days of wound healing and by helping keratinocytes to restore the damaged skin epithelial tissue.

The benefits with Episalvan are its ability to reduce the healing time of wounds where the upper layers of the skin have been damaged, for example by a burn or during surgical skin grafting. The most common side effects are itching and pain in the area where the product is applied and complications in the wound healing process.

The full indication is: "treatment of partial thickness wounds 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.

[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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