EMA/89273/2016
EMEA/H/C/003938

EPAR summary for the public

Episalvan

birch bark extract

This is a summary of the European public assessment report (EPAR) for Episalvan. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Episalvan.

For practical information about using Episalvan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Episalvan and what is it used for?

Episalvan is a medicine used in adults to treat partial-thickness skin wounds. These are wounds where the upper layers of the skin have been lost, for example by a burn or during surgical skin grafting.

Episalvan contains a dry extract from birch bark.

How is Episalvan used?

Episalvan is available as a gel that should be applied as a thin layer (1 mm in thickness) to the wound, which should then be covered by a wound dressing. The gel should be re-applied with every dressing change, until the wound is healed, for up to 4 weeks.

The medicine can only be obtained with a prescription.

How does Episalvan work?

The exact way Episalvan works is not fully understood. It is thought that the active substance in Episalvan, birch bark extract, helps the cells that make up the outer layer of the skin (keratinocytes) grow and move quickly towards the gap created by the wound, therefore helping wounds to heal faster.

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What benefits of Episalvan have been shown in studies?

Episalvan was studied in two main studies involving 217 patients with partial-thickness skin wounds in patients who underwent skin graft surgery. The patients received Episalvan together with wound dressing on one half of the wound, while the other half of the wound was treated with standard wound dressing only. In the first study, the average time from surgery to wound closure was 17.1 days for the wounds treated with standard wound dressing only and 15.5 days for the wounds also treated with Episalvan. The respective times were 16.0 and 15.1 days respectively in the second study.

A third study involved 57 patients with partial-thickness burn wounds who had half their wound treated with Episalvan and the other half with a standard disinfectant gel. Both wound halves were also covered with a wound dressing. The average time to wound closure was 8.8 days for the wounds treated with standard disinfectant gel and 7.6 days for the wounds treated with Episalvan.

What are the risks associated with Episalvan?

The most common side effects with Episalvan are wound complications, pain in the skin (both of which may affect more than 3 in 100 people) and pruritus (itching) (which may affect more 1 in 100 people).

For the full list of all side effects and restrictions reported with Episalvan, see the package leaflet.

Why is Episalvan approved?

Episalvan gel was shown to reduce wound healing times. Although the differences were small they were considered relevant for patients with partial-thickness wounds, which can be difficult to heal and for which treatment options are limited. With regard to safety, no major issues were identified and side effects were manageable. The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Episalvan's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Episalvan?

A risk management plan has been developed to ensure that Episalvan is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Episalvan, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Episalvan

The European Commission granted a marketing authorisation valid throughout the European Union for Episalvan on 14 January 2016.

The full EPAR and risk management plan summary for Episalvan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Episalvan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2016.