



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Ledaga

chlormethine

This is a summary of the European public assessment report (EPAR) for Ledaga. 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 Ledaga.

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

What is Ledaga and what is it used for?

Ledaga is a medicine used to treat adults with a skin cancer called mycosis fungoides-type cutaneous T-cell lymphoma. The medicine contains the active substance chlormethine.

Because the number of patients with this skin cancer is low, the disease is considered 'rare', and Ledaga was designated an 'orphan medicine' (a medicine used in rare diseases) on 22 May 2012.

Ledaga is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' (in this case Caryolysine) containing the same active substance and used for the same purpose. The difference between Ledaga and Caryolysine is that Ledaga is available as a gel and Caryolysine was available as a liquid for diluting before applying to the skin.

How is Ledaga used?

Ledaga can only be obtained with a prescription. Treatment with Ledaga should be started by a doctor with appropriate experience.

Ledaga, which is available as a gel, is applied as a thin film to the affected areas of the skin once a day. It has to be applied with care to stop it getting on areas not affected by the disease. Treatment should be stopped if patients develop blisters or open sores. For further information, see the package leaflet.



How does Ledaga work?

The active substance in Ledaga, chlormethine, belongs to the group of cancer medicines called 'alkylating agents'. Alkylating agents work by attaching to the DNA of cells while the cells are dividing. As a result, cancer cells cannot divide and they eventually die.

What benefits of Ledaga have been shown in studies?

The company provided data from the published literature showing that chlormethine, the active substance in Ledaga, is effective in treating mycosis fungoides-type cutaneous T-cell lymphoma.

In addition, a study involving 260 patients found that Ledaga was at least as effective as an ointment containing the same amount of chlormethine. The ointment's effectiveness was considered comparable to that of the reference medicine, Caryolysine. Effectiveness was measured as complete or partial improvement in the 'CAILS' score, which takes into account different features of the cancer, such as the size and appearance of the skin damage. Ledaga was effective in 58% of patients (76 patients out of 130) after at least 6 months of treatment compared with 48% of patients (62 out of 130) using the ointment.

What are the risks associated with Ledaga?

The most common side effects with Ledaga (which may affect more than 1 in 10 people) are dermatitis (skin inflammation with reddening, rash, pain and burning sensation), skin infection and itching. For the full list of side effects and restrictions, see the package leaflet.

Why is Ledaga approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Ledaga has shown comparable safety and effectiveness to Caryolysine and has shown satisfactory quality. Therefore, the CHMP's view was that, as for Caryolysine, the benefits outweigh the identified risks. The Committee recommended that Ledaga be approved for use in the EU.

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

The company that markets Ledaga will supply materials to prevent accidental contact with the medicine, especially in the eye and the inside of the nose and mouth. The materials will include a sealable, child-resistant plastic bag for safely storing the medicine in a refrigerator, together with a patient alert card with instructions on the correct way to apply the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ledaga have also been included in the summary of product characteristics and the package leaflet.

Other information about Ledaga

The European Commission granted a marketing authorisation valid throughout the European Union for Ledaga on 3 March 2017.

The full EPAR for Ledaga 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 Ledaga, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Ledaga can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/Rare disease designation](http://ema.europa.eu/Find%20medicine/Human%20medicines/Rare%20disease%20designation).

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