European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

ALDARA

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Aldara?

Aldara is a cream containing the active substance imiquimod. It is available as 250 mg sachets, each containing 12.5 mg imiquimod (5%).

What is Aldara used for?

Aldara is used in adults to treat the following skin diseases:

- warts on the genitals and around the anus;
- small basal cell carcinomas (slow-growing types of skin cancer);
- actinic keratoses of the face and scalp (precancerous, abnormal skin growths that develop after too much exposure to sunlight), in patients whose immune system is working normally. It is used when other treatments such as cryotherapy (freezing) cannot be used.

The medicine can only be obtained with a prescription.

How is Aldara used?

The number of times Aldara is applied and the duration of treatment depend on the condition being treated:

- For genital warts, Aldara is applied three times a week for up to 16 weeks.
- For small basal cell carcinomas, the cream is applied five times a week for six weeks.
- For actinic keratoses, it is applied three times a week, for one or two four-week courses, with four weeks between courses.

The cream is applied in a thin layer to the affected areas of skin before sleeping, so that it remains on the skin for a suitable length of time (about eight hours) before being washed off. For further information, see the Package Leaflet.

How does Aldara work?

The active substance in Aldara cream, imiquimod, is an immune response modifier. This means that it uses the immune system, the body's natural defences, to bring about its effect. When imiquimod is applied to the skin, it acts locally on the immune system to trigger the release of cytokines, including interferon. These substances help to kill the viruses that cause warts or the abnormal cells in the skin that develop into skin cancer or keratoses.

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How has Aldara been studied?
In all studies, Aldara was compared with placebo (the same cream but without the active substance).

- Aldara has been studied in 923 patients with genital warts in four main studies lasting 16 weeks. The main measure of effectiveness was the number of patients with total clearance of treated warts.
- Aldara has also been studied in 724 patients with small basal cell carcinomas in two studies where patients were treated for six weeks, and used Aldara or placebo either five times a week or every day. The main measure of effectiveness was the number of patients with total clearance of the tumours after 12 weeks.
- Aldara has also been studied in patients with actinic keratoses in two studies involving a total of 505 patients. The main measure of effectiveness was the number of patients whose keratoses had cleared after one or two four-week courses of treatment.

What benefit has Aldara shown during the studies?
In all studies, Aldara was more effective than placebo.

- In the treatment of genital warts, the total clearance rate across the four main studies was 15 to 52% in the Aldara-treated patients, compared with 3 to 18% in the placebo-treated patients.
- When the results of the two studies in basal cell carcinoma were looked at together, total clearance was seen in 66 to 80% of Aldara-treated patients compared with 0 to 3% in the placebo group. There were no differences between the two dose frequencies.
- In actinic keratoses, complete clearance after one or two courses of treatment was seen in 54 and 55% of Aldara-treated patients in the two studies, compared with 15 and 2% in the placebo-treated patients.

What is the risk associated with Aldara?
The most common side effect with Aldara (seen in more that 1 patient in 10) is a reaction at the site of application of the cream (pain or itching). For the full list of all side effects reported with Aldara, see the Package Leaflet.
Aldara should not be used in people who may be hypersensitive (allergic) to imiquimod or any of the other ingredients.

Why has Aldara been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Aldara's benefits are greater than its risks for the treatment of external genital and perianal warts (condylomata acuminata), small basal cell carcinomas and nonhyperkeratotic, nonhypertrophic actinic keratoses in immunocompetent adult patients when other topical treatment options are contraindicated or less appropriate. The Committee recommended that Aldara be given marketing authorisation.

Other information about Aldara:
The European Commission granted a marketing authorisation valid throughout the European Union for Aldara on 18 September 1998. The marketing authorisation was renewed on 18 September 2003 and on 18 September 2008. The marketing authorisation holder is Meda AB.

The full EPAR for Aldara is available here.

This summary was last updated in 09-2008.