European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

ALTARGO

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 Altargo?
Altargo is an ointment that contains the active substance retapamulin.

What is Altargo used for?
Altargo is an antibiotic medicine. It is used for short-term treatment of superficial skin infections. It can be used to treat impetigo (a skin infection causing crusting scabs), and small infected lacerations (cuts), abrasions (grazes) and wounds that have been sutured (stitched). Altargo should not be used to treat infections known or thought likely to be due to methicillin-resistant *Staphylococcus aureus* (MRSA), as it may not work against this type of infection. However, it may be used to treat infections caused by other types of *Staphylococcus aureus*. Prescribers should consider official guidance on the use of antibacterial agents.
The medicine can only be obtained with a prescription.

How is Altargo used?
Altargo should only be used on the skin. It is applied onto the affected area as a thin layer twice a day for five days. The treated area can be covered with a sterile bandage or gauze dressing. Altargo can be used in patients from the age of nine months, but in patients under 18 years of age, the area to be treated should not be more than 2% of the body's surface. If there is no response to treatment after two to three days, doctors should re-evaluate the patient and consider alternative treatments.

How does Altargo work?
The active substance in Altargo, retapamulin, is an antibiotic belonging to the 'pleuromutilin' class. It is derived from a compound produced by certain types of fungus. It works by blocking the bacteria's ribosomes (the parts of the cells where proteins are produced), inhibiting the growth of the bacteria. The full list of bacteria against which Altargo is active can be found in the Summary of Product Characteristics.

How has Altargo been studied?
The effects of Altargo were first tested in experimental models before being studied in humans. Altargo has been studied in five main studies involving over 3,000 patients aged from 9 months upwards. Two studies were carried out in patients with impetigo. The first compared the effects of five days' treatment with Altargo to those of placebo (a dummy treatment) in 213 patients, and the second compared Altargo to fusidic acid (another antibiotic ointment) in 519 patients. The other three studies

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compared the effects of five days' treatment with Altargo to those of cefalexin (an oral antibiotic medicine): two studies were carried out in a total of 1,918 patients with infected skin wounds, and the final study was carried out in 545 patients with infected dermatitis (skin inflammation). In all five studies, the main measure of effectiveness was the proportion of patients whose infections had cleared up after the end of treatment.

What benefit has Altargo shown during the studies?
In patients with impetigo, Altargo was more effective than placebo, with 119 (85.6%) of the 139 patients using Altargo and 37 (52.1%) of the 71 using placebo responding to treatment. Altargo was at least as effective as fusidic acid, with 314 (99.1%) of 317 and 141 (94.0%) of 150 patients, respectively, responding to treatment. For the treatment of infected skin wounds, Altargo and cefalexin had similar response rates: when the results of both skin wound studies were taken together, around 90% of both groups of patients responded to treatment. However, these two studies found that Altargo was not sufficiently effective in the treatment of abscesses (cavities containing pus) or of infections known or likely to be caused by MRSA.
The data presented were insufficient to support the use of Altargo in the treatment of infected dermatitis.

What is the risk associated with Altargo?
The most common side effect with Altargo (seen in between 1 and 10 patients in 100) is irritation at the site of application. For the full list of all side effects reported with Altargo, see the Package Leaflet.
Altargo should not be used in people who may be hypersensitive (allergic) to retapamulin or any of the other ingredients.

Why has Altargo been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Altargo's benefits are greater than its risks for the short term treatment of the following superficial skin infections:

- impetigo,
- infected small lacerations, abrasions or sutured wounds.

The Committee recommended that Altargo be given marketing authorisation.

Other information about Altargo:
The European Commission granted a marketing authorisation valid throughout the European Union for Altargo to Glaxo Group Ltd on 24 May 2007.

The full EPAR for Altargo can be found here.

This summary was last updated in 07-2007.