EMA/230892/2013
EMEA/H/C/000325

EPAR summary for the public

Vaniqa

eflornithine

This is a summary of the European public assessment report (EPAR) for Vaniqa. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Vaniqa.

What is Vaniqa?

Vaniqa is a white cream that contains the active substance eflornithine (115 mg).

What is Vaniqa used for?

Vaniqa is used for the treatment of facial hirsutism in women. Facial hirsutism is excessive growth on the face of coarse hair, often in a male pattern.

The medicine can only be obtained with a prescription.

How is Vaniqa used?

Vaniqa is applied to clean and dry affected areas of the face and under the chin twice a day (at least eight hours apart). It is applied in a thin layer and rubbed in thoroughly. Improvements may be noticed within eight weeks of starting treatment. Continued treatment is needed to maintain the beneficial effects and may lead to further improvement. Vaniqa should be stopped if no improvements are noticed within four months of starting treatment. Women using Vaniqa may still need to use other means to remove hair (plucking, shaving).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How does Vaniqa work?

The active substance in Vaniqa, eflornithine, works by blocking the action of an enzyme called ornithine decarboxylase. This enzyme is found in the bulb of the hair follicle where it controls hair production. When this enzyme is blocked, the growth of hair is slowed down.

How has Vaniqa been studied?

Vaniqa has been studied in two clinical trials involving 596 women treated for up to 24 weeks with Vaniqa or placebo (a dummy treatment, in this case the cream without any active substance). The effectiveness of the treatment was assessed at the end of the study by a doctor who graded the hirsutism as 'clear/almost clear', 'marked improvement', 'improved' or 'no improvement/worse', 48 hours after women had shaved the treated areas of the face and under the chin.

What benefit has Vaniqa shown during the studies?

Improvement was seen as early as eight weeks after starting treatment. In both studies, significant improvement was seen with Vaniqa compared with placebo. When the results were combined, a successful outcome (graded as 'clear/almost clear' or 'marked improvement') was seen in 35% of the women treated with Vaniqa, compared with 9% of those treated with placebo.

What is the risk associated with Vaniqa?

The most common side effect with Vaniqa (seen in more than 1 patient in 10) is acne. For the full list of all the side effects reported with Vaniqa, see the package leaflet.

Vaniqa should not be used in people who may be hypersensitive (allergic) to eflornithine or any of the other ingredients.

What measures are being taken to ensure the safe use of Vaniqa?

The CHMP decided that Vaniqa's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Vaniqa

The European Commission granted a marketing authorisation valid throughout the European Union, for Vaniqa on 20 March 2001. The marketing authorisation is valid for an unlimited period.

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

This summary was last updated in 04-2013.