EMA/780973/2017
EMEA/H/C/000179

EPAR summary for the public

Zyclara

imiquimod

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

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

What is Zyclara and what is it used for?

Zyclara is a cream used to treat actinic keratosis on the face and balding parts of the scalp. Actinic keratosis is a precancerous, abnormal skin growth that develops after too much exposure to sunlight. Zyclara is used to treat adults whose immune system (the body's natural defences) is working normally when other skin treatments for actinic keratosis cannot be used or are less appropriate. It contains the active substance imiquimod at 3.75% strength (100 mg cream contains 3.75 mg imiquimod).

Zyclara is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but Zyclara is available in a different strength. The reference medicine for Zyclara is Aldara, which contains imiquimod at 5% strength.

How is Zyclara used?

Zyclara is available as a 3.75% cream in individual sachets. It can only be obtained with a prescription.

One or two sachets of Zyclara are applied in a thin layer to the affected areas of the face or balding scalp once a day before bedtime. The cream should remain on the skin overnight (for about 8 hours) before being washed off. Daily treatment should continue for 2 weeks. This is followed by a 2-week break without treatment and then a further 2 weeks of treatment. For further information, see the package leaflet.

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The patient's response to treatment should be evaluated 8 weeks after the end of treatment, and a third 2-week course may be considered if needed. If actinic keratosis does not improve enough with Zyclara, a different treatment should be tried.

If actinic keratosis is cleared after two 2-week courses but then it comes back, it can be treated again with one or two 2-week treatment courses provided these are given after a break of at least 12 weeks from the original treatment.

How does Zyclara work?

The active substance in Zyclara cream, imiquimod, is an immune response modifier. This means that it uses the immune system 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 abnormal cells in the skin that lead to keratosis.

What benefits of Zyclara have been shown in studies?

Zyclara has been shown to be effective in clearing actinic keratosis from the skin in two main studies involving 479 patients with actinic keratosis on the face and scalp. Two doses of Zyclara (2.5% and 3.75%) were compared with placebo (a dummy treatment) in these studies, and the main measure of effectiveness was the number of patients whose skin was completely cleared of the actinic keratosis after treatment. Around 36% of patients treated with Zyclara 3.75% cream in the two studies had complete clearance compared with around 6% of patients treated with placebo. Zyclara at a lower strength (2.5%) had a lower clearance rate than the 3.75% strength.

What are the risks associated with Zyclara?

Most patients using Zyclara experience side effects on the skin where the medicine was applied (most commonly redness, scab formation, dryness and shedding of the skin). About 11% of patients in studies with Zyclara required treatment to be interrupted due to this kind of side effect on the skin. Some other side effects, including headache and tiredness, were also reported. For the full list of side effects and restrictions with Zyclara, see the package leaflet.

Why is Zyclara approved?

The European Medicines Agency concluded that Zyclara 3.75% cream has been shown to be effective at clearing actinic keratosis from the skin and that its use did not raise significant safety concerns. Treatment with Zyclara has the advantage of being easier to adhere to than Aldara treatment because it has a simpler dosing regimen. In addition, its lower strength allows it to be used across larger areas of the skin and thereby treat more of the affected skin.

The Agency therefore decided that Zyclara's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Zyclara

The European Commission granted a marketing authorisation valid throughout the European Union for Zyclara on 23 August 2012.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 12-2017.