Zyclara 3.75% cream

Imiquimod

Read all of this leaflet carefully before you start using this medicine. Zyclara contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist.

1. What Zyclara is and what it is used for

Zyclara 3.75% cream contains the active substance imiquimod, which is an immune response modifier (stimulates the human immune system). This medicine is prescribed for the treatment of actinic keratosis in adults. This medicine stimulates your body’s own immune system to produce natural substances which help fight your actinic keratosis.

Actinic keratosis appears as rough areas of skin found in people who have been exposed to a lot of sunshine over the course of their lifetime. These areas can be the same colour as your skin or are grey, pink, red or brown. They can be flat and scaly, or raised, rough, hard and warty. This medicine should only be used for actinic keratosis on the face or scalp if your doctor has decided that it is the most appropriate treatment for you.

2. What you need to know before you use Zyclara

Do not use Zyclara if:
- you are allergic to imiquimod or any of the other ingredients of this product (see section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Zyclara:
- if you have previously used this medicine or other similar preparations in a different preparation.
- if you have problems with your immune system or if you take medicines to suppress your immune system (e.g. after an organ transplant)
- if you have an abnormal blood count.

General instructions during treatment

If you have recently had surgical treatment or hospital treatment, wait until the area to be treated has healed before using this medicine.

- Avoid contact with the eyes, lips and nostrils. In the event of accidental contact, remove cream by washing with water.
- Only use the cream externally (on the skin) of face or scalp.
- Do not use more cream than you have been told to use.
- Do not cover the treated area with bandages or other dressings after you have had any medicine treatment.
- If the treated site becomes too uncomfortable, wash the cream off with mild soap and water. Once the discomfort stops you can resume your treatment schedule as recommended. The cream should not be applied over more than 96% of your body.
- Do not use sunlamps or tanning-beds, and avoid exposure to sunlight as much as possible during treatment with this medicine. If you go outside during the day use sunscreen and wear protective clothing and a wide-brimmed hat.

Local skin reactions

While using cream, you may experience local skin reactions because of the way it acts on your skin. These reactions can be a sign that the medicine is working as intended.

- While using Zyclara, the treated area is likely to appear noticeably different from normal skin. This is also a possibility that existing inflammation may temporarily worsen.

- This medicine may also cause skin reactions (including redness, burning, itching, pain, drying, scaling, skin dryness, skin swelling, skin irritation, and skin thickening) in a small area of the skin. This can occur some time after you have stopped using the medicine.

- Do not use Zyclara if you have a severe allergy to any of the ingredients listed in section 6.

How to use Zyclara

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not use this medicine until your doctor has seen you again and told you to use it. This medicine should only be used for actinic keratosis on the face and scalp.

Dermatitis

Apply the cream to the affected area once a day just before bedtime. Maximum daily dose is 2 capsules (50 mg + 2 capsules of 250 mg each). This medicine should not be applied to areas larger than either the full face or half scalp.

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.