Zyclara 3.75 % cream

Iniquimod

Read all of this leaflet carefully before you start using this medicine because it 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. This includes possible side effects not listed in this leaflet. See section 4.

What is this leaflet

1. What Zyclara is and what it is used for

Zyclara 3.75 % cream contains the active substance imiquimod. 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 greyish, pink, red or brown. They can be flat and easy, 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 your condition.

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 medicine (listed in 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 concentration.
- if you have problems with your immune system or if you take medicine 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 surgery or medical 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 than the stated time of treatment.

Diet or alcohol

- None known.

Method of administration

- Before going to bed, wash your hands and the treatment area carefully with mild soap and water. Dry hands thoroughly and allow the area to dry.
- Open a new sachet of Zyclara just before use (see section 5). Do not open the sachets before use.
- Apply a thin layer of Zyclara to the affected area.
- Rub gently into the area until the cream vanishes.
- Avoid contact with the eyes, lips and nostrils.

Duration of treatment

The treatment starts with a daily application for two weeks, followed by a break without any application for two weeks, then ends with a daily application again for two weeks.

If you use more or less than Zyclara than you should

If you have applied too much cream, wash the extra away with mild soap and water.

If this medicine has reacted with your skin then you may continue with your treatment in the recommended regular schedule. The cream should not be applied more than once daily. Each treatment cycle should last no longer than two weeks, even if you have missed doses.

If you stop using Zyclara

Talk to your doctor before you stop treatment with Zyclara.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Seek medical attention right away if any of these severe side effects occur when using this medicine:

- Serious skin reactions with blisters or spots on your skin that start as small red areas and progress to look like minor targets, possibly with symptoms such as itching, fever, overall ill feeling, skin justices, vision problems, burning, painful or itchy eyes and mouth sores.

If you experience these, stop using this medicine and tell your doctor immediately.

In some individuals a lowering of blood counts was noted. This might make you more susceptible to infections, make you more each or cause tiredness.

If you notice any of these signs, tell your doctor. There is no cure for another sign of infection, discuss this with your doctor.

Some of the side effects of this medicine are due to its local action on your skin. Local skin reactions can be a sign that the medication is working as intended. If your skin reacts badly or becomes uncomfortable when using this medicine, stop applying the cream and wash off the cream with mild soap and water. Then contact your doctor or pharmacist. He may advise you to stop applying this medicine for a few days (i.e. during a short rest from treatment).

The following side effects with imiquimod were reported:

Common (may affect more than 1 in 10 people)
- Sore or redness of the skin in the area treated with the cream.
- Dryness.
- Stinging.
- Swelling.
- Itching.
- Skin irritation.
- Redness.
- Pain.
- Muscle and joint pain.
- Inflamed.
- Irritated.
- Viral infection (herpes simplex)
- Discomfort.
- Irritation.
- Weakness.

Required (may affect 1 in 10 to 100 people)
- Numbness or tingling in the skin.
- Skin rash.
- Skin thinning.
- Skin dryness.
- Skin erosion.
- Skin color.
- Skin reaction.
- Skin irritation.
- Skin infection.
- Skin change.
- Skin rash.

Rare (may affect up to 1 in 1,000 people)
- Eruption of one or more muscle or joint pains.
- Stomach ache.
- Sleep disorder.
- Hair loss.
- Skin rash.

- Changes in skin colour
- Some patients have experienced changes in skin colour in the area where Zyclara was applied.

While these changes have tended to improve with time, in some patients they may be permanent.

- Hair loss
- A small number of patients have experienced hair loss at the treatment site or surrounding area.
- Increase in liver enzymes
- There have been reports of increased liver enzymes.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes possible side effects not listed in this leaflet. You can also report side effects directly via (see details below).

By reporting side effects you can help to provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance

European Tariff

IRL - Dublin 2

Tel: +353 1 6784971

Fax: +353 1 6762117

Website: www.hpra.ie

e-mail: madalyn@hpria.ie

Malta

Mag Report

Website: www.medicinesauthority.gov.mt/madportal

5. How to store Zyclara

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the outer carton and the blister pack.

The expiry date refers to the last day of that month.

Do not store above 20 °C.

Sachets should not be re-used once opened.

- Do not throw away any medicines via wastewater or household waste.
- Ask your pharmacist how to throw away medicines you no longer use.
- These measures will help to protect the environment.

6. Contents of the pack and other information

What Zyclara contains

The active substance is imiquimod. Each sachet contains 9.375 mg of imiquimod in 250 mg cream (100 mg of cream contains 3.75 mg imiquimod).

- The other ingredients are isonicotinic acid, benzyl alcohol, propylene glycol, arbutin stearate, glycerol, methyl parahydroxybenzoate (E 219), propyl parahydroxybenzoate (E 218), Methyl parahydroxybenzoate (E 218), and propyl parahydroxybenzoate (E 218).

What Zyclara looks like and contents of the pack

- Each Zyclara 3.75 % cream sachet contains 250 mg of a white to slightly yellow cream with a uniform appearance.

- Each box contains 14, 28 or 56 single-use polyester/ white low density polyethylene/aluminium foil sachets. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

MediAll

Papierweg 2A

70 775 Selms

Germany

Manufacturer

3M Health Care Limited

Loddington

Leston

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DK 06 10 3:17

3442375

PK06072

056913891
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This leaflet was last revised in (09/2015).

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