Package leaflet: Information for the user

Zyclara 3.75 % cream
imiquimod

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 sign of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zyclara is and what it is used for
2. What you need to know before you use Zyclara
3. How to use Zyclara
4. Possible side effects
5. How to store Zyclara
6. Content of the pack and other information

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 (to stimulate 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 greyish, 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 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 suffer from autoimmune disorders
- if you have had an organ transplant

- if you have an abnormal blood count.

General instructions during treatment

- If you have recently had surgery or medicinal 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 rinsing with water.
- Only use the cream externally (on the skin of face or scalp).
- Do not use more cream than your doctor has advised.
- Do not cover the treated area with bandages or other dressings after you have applied this medicine.
- 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 more than once daily.
- 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 Zyclara, 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.

Whilst using Zyclara and until healed, the treatment area is likely to appear noticeably different from normal skin. There is also a possibility that existing inflammation may temporarily worsen.
This medicine may also cause flu-like symptoms (including tiredness, nausea, fever, muscle and joint pain, and shivering) before or during the occurrence of local skin reactions.
If flu-like symptoms or feeling discomfort or intense local skin reactions occur, a rest period of several days may be taken. You could resume treatment with imiquimod cream after the skin reaction has moderated. However, neither 2-week treatment cycle should be extended due to missed doses or rest periods.
The intensity of the local skin reactions tends to be lower in the second cycle than in the first treatment cycle with Zyclara.

Response to treatment cannot be adequately assessed until resolution of local skin reactions. You should continue treatment as prescribed.
This medicine may reveal and treat actinic keratosis that have not be seen or felt before, and these may later go away. You should continue application for the full treatment course even if all actinic keratosis appear to be gone.

Children and adolescents

This medicine should not be given to children below the age of 18 years because the safety and efficacy in patients below the age of 18 years have not been established. There are no data available of the use of imiquimod in children and adolescents.

Other medicines and Zyclara

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you receive immunosuppressive medicinal products which inhibit the immune system, tell your doctor before starting the treatment.
Avoid the concomitant use of Zyclara and any other imiquimod cream in the same treatment area.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Your doctor will discuss the risks and benefits of using Zyclara during pregnancy. Studies in animals do not indicate direct or indirect harmful effects in pregnancy.

It is not known whether imiquimod passes into breast milk. You should not use Zyclara if you are breast-feeding or plan to breast-feed. Your doctor will discuss if you should discontinue breast-feeding or discontinue Zyclara treatment.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines.

Zyclara contains methyl parahydroxybenzoate, propyl parahydroxybenzoate, cetyl alcohol, stearyl alcohol and benzyl alcohol

Methyl parahydroxybenzoate (E 218), and propyl parahydroxybenzoate (E 216), may cause allergic reactions (possibly delayed). Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).
This medicine contains 5 mg benzyl alcohol in each sachet. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use Zyclara

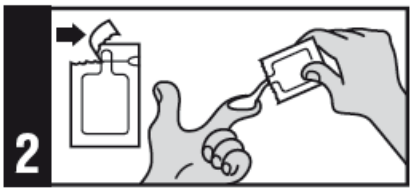
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not use this medicine until your doctor has shown you the right way to use it.

This medicine should only be used for actinic keratosis on the face and scalp.

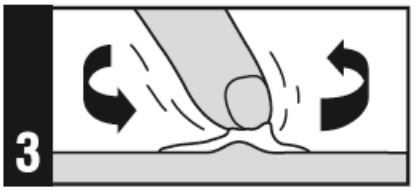
Dosage
Apply this medicine to the affected area once a day just before bedtime.
Maximum daily dose is 2 sachets (500 mg = 2 sachets of 250 mg each).
This medicine should not be applied to areas larger than either the full face or balding scalp.

Method of administration

1. 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.



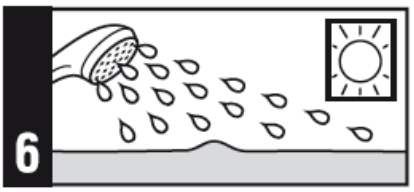
2. Open a new sachet of Zyclara just before use and squeeze some cream onto your fingertip. No more than 2 sachets should be used per application.



3. 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.

4. After application of the cream, throw away the opened sachet. Wash hands well with soap and water.

5. Leave Zyclara on the skin for about 8 hours. Do not shower or bathe the area during this time. Do not cover the treated area with bandages or other dressings.



6. After about 8 hours, wash the area where Zyclara was applied with mild soap and water.

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

If you use more Zyclara than you should

If you have applied too much cream, wash the extra away with mild soap and water.
When any skin reaction has gone you may then continue with your treatment in the recommended regular schedule. The cream should not be applied more than once daily.

If you accidentally swallow this medicine, please contact your doctor immediately.

If you forget to use Zyclara

If you miss a dose of Zyclara, wait until the next night to apply it and then continue with the 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 (frequency not known) with skin lesions or spots on your skin that start out as small red areas and progress to look like mini targets, possibly with symptoms such as itching, fever, overall ill feeling, achy joints, 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 (frequency not known). This might make you more susceptible to infections, make you bruise more easily or cause tiredness. If you notice any of these symptoms, tell your doctor.
Some patients who suffer from autoimmune disorders may experience worsening of their condition. If you notice any change during treatment with Zyclara, tell your doctor.
If there is pus or another sign of skin infection (frequency not known), discuss this with your doctor.

Many 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 medicine is working as intended. If your skin reacts badly or becomes too uncomfortable when using this medicine, stop applying the cream and wash the area 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. to have a short rest from treatment).

The following side effects with imiquimod were reported:

Very common (may affect more than 1 in 10 people)
- Skin redness, scabbing, skin scaling, discharge, skin dryness, skin swelling, skin ulcer, and reduced skin pigmentation at the application site

Common (may affect up to 1 in 10 people)
- Further reactions at the application site e.g. skin inflammation, itching, pain, burning, irritation, and rash
- Swollen glands
- Headache
- Dizziness
- Loss of appetite
- Nausea
- Diarrhoea
- Vomiting
- Flu-like symptoms
- Fever
- Pain
- Muscle and joint pain
- Chest pain
- Insomnia
- Tiredness
- Viral infection (herpes simplex)
- Increase in blood glucose

Uncommon (may affect up to 1 in 100 people)
- Changes at the application site, e.g. bleeding, small swollen areas in the skin, inflammation, pins and needles, increased sensitivity to touch, scarring, feeling of warmth, skin breakdown, blisters or pustules
- Weakness
- Shivering
- Lack of energy (lethargy)
- Discomfort
- Swelling of the face
- Back pain
- Pain in limbs
- Stuffy nose

- Throat pain
- Eye irritation
- Swelling of the eyelid
- Depression
- Irritability
- Dry mouth
- Abdominal pain

Rare (may affect up to 1 in 1,000 people)

- Flaring up of autoimmune conditions (a disease that results from an abnormal immune response is an autoimmune disease)
- Skin reactions remote from the application site

Frequency not known (frequency cannot be estimated from the available data)

- 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 any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard
Or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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 label after EXP.
The expiry date refers to the last day of that month.
Do not store above 25 °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 isostearic acid, benzyl alcohol, cetyl alcohol, stearyl alcohol, white soft paraffin, polysorbate 60, sorbitan stearate, glycerol, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), xanthan gum, purified water (see also section 2 “Zyclara contains methyl parahydroxybenzoate, propyl parahydroxybenzoate, cetyl alcohol, stearyl alcohol and benzyl alcohol”).

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 Authorisation Holder

Viatris Products Limited,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer

Swiss Caps GmbH
Grassingerstraße 9
83043 Bad Aibling
Germany

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