IKERVIS® 1MG/ML EYE DROPS, EMULSION

Ciclosporin A (1mg/1ml)

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What Ikervis is used for

Ikervis is used to treat adults with severe keratitis (inflammation of the cornea, the transparent layer in the front part of the eye). It is used in those patients who have dry eye disease, which has not improved despite treatment with tear substitutes (artificial tears).

Ikervis is also used to treat severe vernal keratoconjunctivitis (VKC) in children and adolescents from 4 to 18 years old.

Talk to a doctor if you do not feel better or if you feel worse.
You should visit your doctor at least every 6 months to assess the effect of Ikervis.

How Ikervis works

Ikervis contains the active substance ciclosporin. Ciclosporin belongs to a group of medicines known as immunosuppressive agents. These medicines are used to reduce inflammation.

Before you use Ikervis

- *When you must not use it*

Do NOT use Ikervis:

- If you are allergic to ciclosporin or any of the other ingredients of this medicine (listed in section "Ingredients").
- if you have had or have a cancer in or around your eye.
- If you have an eye infection.

- *Before you start to use it*

Talk to your doctor or pharmacist before using Ikervis.

For treatment of severe keratitis in dry eye disease

- If you have previously had an eye infection by the herpes virus that might have damaged the transparent front part of the eye (cornea).
- If you are taking any medicines containing steroids.
- If you are taking any medicines to treat glaucoma.

Contact lenses can further damage the transparent front part of the eye (cornea). Therefore, you should remove your contact lenses at bedtime before using Ikervis; you can reinsert them when you wake up.

For treatment of severe VKC

- If you had an eye infection or if you suspect you have an eye infection.
- If you have any other kind of eye disease.
- If you wear contact lenses (the use of IKERVIS is not recommended with contact lenses).

Taking other medicines

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicine.

Talk to your doctor if you are using eye drops containing steroids with Ikervis as these might increase the risk of side effects.
If you are using IKERVIS for treatment of severe VKC for more than 12 months, you should visit your doctor regularly, e.g. every 3 to 6 months.
Ikervis eye drops should be used at least 15 minutes after any other eye drops are used.

How to use Ikervis

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to use

For treatment of severe keratitis in dry eye disease: The recommended dose is one drop in each affected eye, once daily at bedtime.

For treatment of severe VKC: The recommended dose is one drop in each affected eye, 4 times a day (morning, mid-day, afternoon and evening).

When to use it

For treatment of severe keratitis in dry eye disease: Once daily at bedtime

For treatment of severe VKC: 4 times a day (morning, mid-day, afternoon and evening).

- *How long to use it*

Do not stop using Ikervis unless your doctor instructs you to do so.
If you have any further question on the use of this medicine, ask your doctor or your pharmacist.

- *If you forget to use it*

If you forget to use Ikervis, continue with the next dose as planned.
Do not take a double dose to make up for the forgotten dose. Do not use more than one drop in the affected eye(s).

- *If you use too much (overdose)*

If you use more Ikervis than you should, rinse your eye with water. Do not put in any more drops until it is time for your next regular dose.

While you are using it

- *Things you must do*
  - Keep this leaflet. You may need to read it again.
  - If you have any further questions, ask your doctor or your pharmacist.
  - If you have any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section "Side effects".

- *Things you must not do*

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.

- *Things to be careful of*

This medicine may cause blurred vision temporarily after applying. Do not operate machinery or drive a car until these symptoms recover.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think that you may be pregnant or are planning

to have a baby, ask your doctor or pharmacist for advice before using this medicine.
Ikervis should not be used if you are pregnant. If you could become pregnant you must use contraception while using this medicine.
Ikervis is likely to be present in breast milk in very small amounts. If you are breast feeding, talk to your doctor before using this medicine.

Children and adolescents
For treatment of severe keratitis in dry eye disease, IKERVIS should not be used in children and adolescents below 18 years old.
For treatment of severe VKC, IKERVIS should not be used in children under the age of 4 years.

Driving and using machines
Your vision may be temporarily blurred immediately after using IKERVIS eye drops or you may get other disturbances with your vision. If this happens, wait until your vision clears before you drive or use machines.

IKERVIS contains cetalkonium chloride
This medicine contains 0.05 mg cetalkonium chloride in 1 mL You should remove contact lenses before using this medicine and you can reinsert them when you wake up. Cetalkonium chloride may cause eye irritation. If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

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

The following side effects have been reported:
The most common side effects are in and around the eyes.

<u>*Treatment of severe keratitis in dry eye disease*</u>:
Very common (may affect more than 1 in 10 people)
- Eye pain,
- Eye irritation

Common (may affect up to 1 in 10 people)
- Redness of the eyelid,
- Watery eyes,
- Eye redness,
- Blurred vision,
- Swelling of the eyelid,
- Redness of the conjunctiva (thin membrane covering the front part of the eye)
- Itching in the eye

Uncommon (may affect up to 1 in 100 people)
- Discomfort in or around the eye when the drops are put into the eye, including feeling that there is something in the eye,
- Irritation or swelling of the conjunctiva (thin membrane covering the front part of the eye),
- Tear disorder,
- Eye discharge,
- Irritation or inflammation of the conjunctiva (thin membrane covering the front part of the eye),
- Inflammation of the iris (coloured part of the eye) or eyelid,
- Deposits in the eye,
- Abrasion to the outer layer of the cornea,
- Red or swollen eyelids,
- Cyst in the eyelid,
- Immune response or scarring in the cornea
- Itching in the eyelid,
- Bacterial infection or inflammation of the cornea (transparent front part of the eye),
- Painful rash around the eye caused by the herpes zoster virus,
- Headache

<u>*Treatment of severe VKC*</u>:
Very common side effects (may affect more than 1 in 10 people)
– Pain when the drops are put into the eye.

Common side effects (may affect up to 1 in 10 people)
Common side effects related to the eye:
- Itching, redness, irritation and discomfort in or around the eye including a feeling that there is something in the eye. Increased watering of the eye and blurred vision when the drops are put into the eye. Swelling and redness of eyelid.

Common side effects which are not related to the eye:
- Upper respiratory tract infection, cough, headache.

Uncommon side effects (may affect up to 1 in 100 people)
- Swelling of the eyelid and of the conjunctiva (thin membrane covering the front part of the eye). Bacterial infection of the cornea (transparent front part of the eye). Eye infection caused by herpes zoster virus.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website <u>npra.gov.my</u> (Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of Ikervis
- <u>*Storage*</u>

Do not store above 30°C.Protect from light. Do not freeze.
Keep this medicine out of the sight and reach of children.
After opening of the aluminium pouches, the single-dose containers should be kept in the pouches in order to protect from light and avoid evaporation. Any opened individual single-dose container with any remaining emulsion should be discarded immediately after use.

- <u>*Disposal*</u>

Do not use this medicine after the expiry date which is stated on the outer carton, the aluminium pouch and the single-dose container after "EXP". The expiry date refers to the last day of that month.

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

Product Description
– <u>*What it looks like*</u>

Ikervis is a milky white eye drops emulsion.
It is supplied in single-dose containers

made of a low-density polyethylene (LDPE). Each single-dose container contains 0.3ml eye drops, emulsion.
The single-dose containers are wrapped in a sealed aluminium pouch.

– *Ingredients*

- Active ingredient:
  One mL of emulsion contains 1mg of Ciclosporin.

– *Inactive ingredients:*

- Medium-chain triglycerides, Cetalkonium chloride, Glycerol, Tyloxapol, Polyxamer 188, Sodium hydroxide, Water for injections.

– *MAL number(s):*
MAL18026001ACRZ

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