

Consumer Medicine Information

This leaflet provides important information about using IKERVIS®. **You should also speak to your doctor, optometrist or pharmacist if you would like further information or if you have any concerns or questions about using IKERVIS®.**

Where to find information in this leaflet:

1. Why am I using IKERVIS®?
2. What should I know before I use IKERVIS®?
3. What if I am taking other medicines?
4. How do I use IKERVIS®?
5. What should I know while using IKERVIS®?
6. Are there any side effects?
7. Product details

1. Why am I using IKERVIS®?

IKERVIS® contains the active ingredient ciclosporin. Ciclosporin belongs to a group of medicines known as immunosuppressive agents that are used to reduce inflammation.

IKERVIS is used to treat adults with severe keratitis (inflammation of the cornea, the transparent layer in the front part of the eye) as a result of dry eye disease, which has not improved despite treatment with tear substitutes (artificial tears).

2. What should I know before I use IKERVIS®?**Warnings****Do not use IKERVIS® if:**

- you are allergic to ciclosporin, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- you have or have had a cancer in or around your eye
- you have an eye infection.

Check with your doctor if you:

- have any other medical conditions, in particular, any conditions which affect your eyes
- take medicines for any other condition, particularly medicines that belong to a group called steroids or medicines used to treat glaucoma
- if you have previously had an eye infection caused by the herpes virus that might have damaged the transparent front part of the eye (cornea).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Contact Lenses

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.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

IKERVIS® should not be used if you are pregnant or planning to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if IKERVIS® passes into breast milk.

Adolescent and children under 18 years.

IKERVIS® should not be used in children and adolescents under the age of 18 years.

3. What if I am taking other medicines?

Tell your doctor, optometrist or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Co-administration of IKERVIS® with eye drops containing corticosteroids could increase the effects of ciclosporin on the immune system. This could increase the risk of side effects.

IKERVIS® eye drops should be used at least 5 minutes after any other eye drops are used.

Check with your doctor, optometrist or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IKERVIS®.