

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Oculac 50 mg/ml eye drops, solution in single-dose containers Povidone K25

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

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- 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 any side effects not listed in this leaflet

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

What is Oculac and what it is used for

Oculac contains the active substance povidone K25. Oculac is an eye drop to moisten and lubricate the eyes. It is used to relieve the symptoms of dry eyes.

2. What you need to know before you use Oculac

Do not use Oculac

If you are allergic to povidone K25 or any of the other ingredients of this medicine (please refer to section 6). If you think you may be allergic, do not use this medicine before talking to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before Oculac eye drops.

If you experience headache, eye pain, vision changes, irritation of the eyes, persistent redness or if the condition persists or worsens, Oculac eye drops should be discontinued and a doctor should be consulted.

Other medicines and Oculac

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

If you need to apply any other medicinal products to your eyes together with Oculac, you should wait at least 5 minutes between applying each product and always apply Oculac last.

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. Oculac can be used during pregnancy and breast-feeding.

Driving and using machines

Oculac may cause blurred vision. If this happens to you, wait until this has cleared before driving or operating machinery.

3. How to use Oculac

Always use this medicine exactly as described on this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one drop in the eye four times daily or as required.

One single-dose container contains enough solution to treat both eyes in one application.

If a drop misses your eye, try again.

If you use more Oculac eye drops than you should, no undesirable effects are to be expected.

If you are using other eye drop or eye ointment medicines, leave at least 5 minutes between each medicine. Oculac should be administered last.

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

Instructions for use

1. Wash your hands.
2. Remove one of the single-dose containers from the strip (Fig. 1).
3. Place the remaining single-dose containers back in the carton.
4. Open the single-dose container by twisting off the tip. Do not touch the tip after opening the container as it may contaminate the solution (Fig 2).
5. Lean your head back (Fig. 3).
6. Pull down your lower eyelid with your finger and hold the container in your other hand. The tip of the container should not come in contact with eye as it may cause injury to the eye. Squeeze the container so that one drop falls into the eye (Fig 4).
7. Close your eyes and press the tip of one finger against the inner corner of the eye for around 1-2 minutes. This will prevent the drop running through the tear duct into your throat and most of the drop will remain in the eye (Fig 5). If necessary repeat steps 5 to 7 with your other eye.
8. Discard the container after use.



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5

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

4. Possible side effects

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

The following side effects have been reported:

Common (may affect up to 1 in 10 people)

- slight, temporary burning or sticky sensation in the eye(s)

Very rare (may affect up to 1 in 10,000 people)

- irritation
- allergic reactions

Not known (*cannot be estimated from the available data*):

- blurred vision, eye pain, eye itching, redness of the eye.

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oculac

Keep out of sight and reach of children.

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

The single-dose container is not sterile itself, but its contents are sterile until the container is opened.

Once opened, the contents of the single-dose container must be used immediately and not saved.

Do not use Oculac after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Oculac contains

The active substance is povidone K25. Each ml contains 50 mg povidone K25.

The other ingredients are boric acid, calcium chloride, potassium chloride, magnesium chloride, sodium chloride, sodium lactate, sodium hydroxide for pH adjustment, and purified water /water for injections.

The product does not contain any preservative.

What Oculac looks like and contents of the pack

Oculac is a slightly yellowish, clear aqueous solution. One single-dose container contains 0.4 ml. They are supplied in packs containing 20, 60 or 120 single-dose containers. Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

<To be completed nationally

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

Manufacturer

<To be completed nationally>

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Oculac (SDU)
Finland	Oculac (SDU)
Portugal	Oculotect Unidoses
Spain	Oculotect 50 mg/ml colirio en solución en envase unidosis
Sweden	Oculac

This leaflet was last approved in 1 December 2025

<To be completed nationally>