PATIENT INFORMATION
OXERVATE® (ox'-er-vayt)
(cenegermin-bkbj)
ophthalmic solution, for topical ophthalmic use

What is OXERVATE®?
OXERVATE is a prescription eye drop solution used to treat a condition called neurotrophic keratitis.

OXERVATE is safe and effective in children two years of age and older.

Before you use OXERVATE, tell your doctor about all of your medical conditions, including if you:

- have an infection in your eye. If you get an eye infection **while** using OXERVATE, talk to your doctor right away.
- are using any other eye drops.
- wear contact lenses.
- are pregnant or plan to become pregnant. It is not known if OXERVATE will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OXERVATE passes into your breast milk. Talk to your doctor about the best way to feed your baby if you use OXERVATE.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use OXERVATE?

- See the complete Instructions for Use at the end of this Patient Information leaflet for detailed instructions about the right way to use OXERVATE.
- Use OXERVATE exactly as your doctor tells you.
- Use 1 drop of OXERVATE in the affected eye or both eyes if needed, 6 times each day, about 2 hours apart starting in the morning. Continue your treatment for 8 weeks.
- If you use any other eye drops, wait **at least 15 minutes before or after** using OXERVATE. This will help to avoid one eye drop diluting the other eye drop.
- If you also use an eye ointment or gel or an eye drop that is thick, use OXERVATE **first**, and then wait **at least 15 minutes before** using the other eye ointment, gel, or drops.
- If you wear contact lenses in your affected eye or both eyes remove them before using OXERVATE and **wait 15 minutes after** using OXERVATE before reinserting them.
- If you miss a dose of OXERVATE, take your next dose at your scheduled time. **Do not** take an extra dose to make up for a missed dose.
- **Do not** use other eye medicines without talking to your doctor.
- Talk to your doctor first before you stop using OXERVATE.
- If you have any questions about how to use OXERVATE, ask your doctor or pharmacist.

What should I avoid while using OXERVATE?
Your vision may be blurred for a short time after using OXERVATE. If this happens, **wait until your vision clears before you drive or use machines**.

What are the possible side effects of OXERVATE?
The most common side effects of OXERVATE are eye pain, enlarged blood vessels in the white of the eyes (ocular hyperemia), swelling (inflammation) of the eye, and increase of tears (increased lacrimation).

Tell your doctor if you have any side effects that bother you. These are not all the possible side effects of OXERVATE. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of OXERVATE.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use OXERVATE for a condition for which it was not prescribed. Do not give OXERVATE to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or doctor for information about OXERVATE that is written for health professionals.

What are the ingredients in OXERVATE?

Active ingredient: cenegermin-bkbj

Inactive ingredients: disodium hydrogen phosphate anhydrous, hydroxypropylmethyl cellulose, L-methionine, mannitol, polyethylene glycol 6000, sodium dihydrogen phosphate dihydrate, trehalose dihydrate, Water for Injection, USP, and hydrochloric acid and/or sodium hydroxide to adjust pH.

Manufactured by:
Dompé farmaceutici S.p.A.
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67100 L'Aquila, Italy
U.S. License No. 2074

Manufactured for: Dompé U.S. Inc.

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For more information, go to www.oxervate.com or call 1-833-366-7387.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: December 2024