oxervate®
(cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL)

CORNEAL INTEGRITY MATTERS

WHAT NK DAMAGES, OXERVATE® HEALS.[1,2]

The first and only FDA-approved treatment option for neurotrophic keratitis (NK).[1,*]



Prescribed by [more than 9000] eye care professionals to [more than 40,000] patients since its approval in 2018.[3]

*The efficacy and safety of OXERVATE were studied in 151 patients across two 8-week, randomized, multi-center, double-masked, vehicle-controlled studies (NGF0212 and NGF0214). In NGF0212, 72.0% of the OXERVATE group (n=36/50) and 33.3% of the vehicle group achieved complete corneal healing (n=17/51; 38.7% difference; 95% CI: 20.7%, 56.6%; *P*<0.01). In NGF0214, 65.2% of the OXERVATE group (n=15/23) and 16.7% of the vehicle group achieved complete corneal healing (n=4/24; 48.6% difference; 95% CI: 24.0%, 73.1%; *P*<0.01). Complete corneal healing was defined as the absence of staining of the corneal lesion and no persistent staining in the rest of the cornea at 8 weeks of treatment. Patients without post-baseline measurements were excluded.[1]

INDICATION

OXERVATE (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) is indicated for the treatment of neurotrophic keratitis.

Important Safety Information

WARNINGS AND PRECAUTIONS

Use with Contact Lens

Contact lenses should be removed before applying OXERVATE because the presence of a contact lens (either therapeutic or corrective) could theoretically limit the distribution of cenegermin-bkbj onto the area of the corneal lesion. Lenses may be reinserted 15 minutes after administration.

Eye Discomfort

OXERVATE may cause mild to moderate eye discomfort such as eye pain during treatment. The patient should be advised to contact their doctor if a more serious eye reaction occurs.

Please see additional Important Safety Information throughout and full Prescribing Information for OXERVATE.

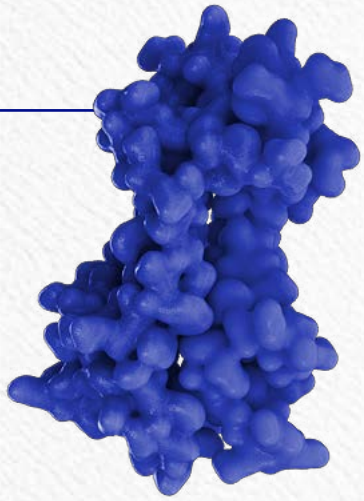
OXERVATE® works *beyond* the ocular surface to support corneal nerve health[1]

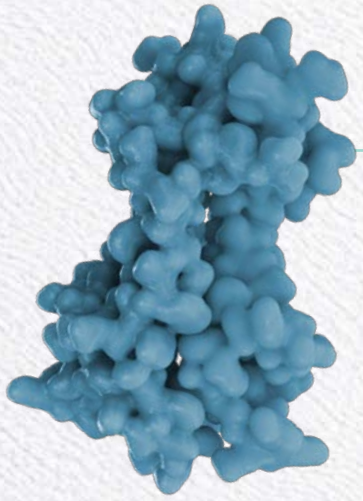


OXERVATE is structurally identical to human nerve growth factor (NGF)[4]

OXERVATE[1]

Addresses the underlying nerve damage that drives NK progression through a recombinant human nerve growth factor (rhNGF).





NGF[1,2]

Endogenous NGF supports corneal nerve integrity and contributes to ocular surface homeostasis.*

NGF supports:

- Corneal integrity
- Tear secretion
- Epithelial cell growth

*Based on preclinical models.[2]

Important Safety Information (cont'd)

ADVERSE REACTIONS

In clinical trials, the most common adverse reaction was eye pain following instillation which was reported in approximately 16% of patients. Eye pain may arise as corneal healing occurs. Other adverse reactions occurring in 1% to 10% of OXERVATE patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation, photophobia, tearing, and headache.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks.

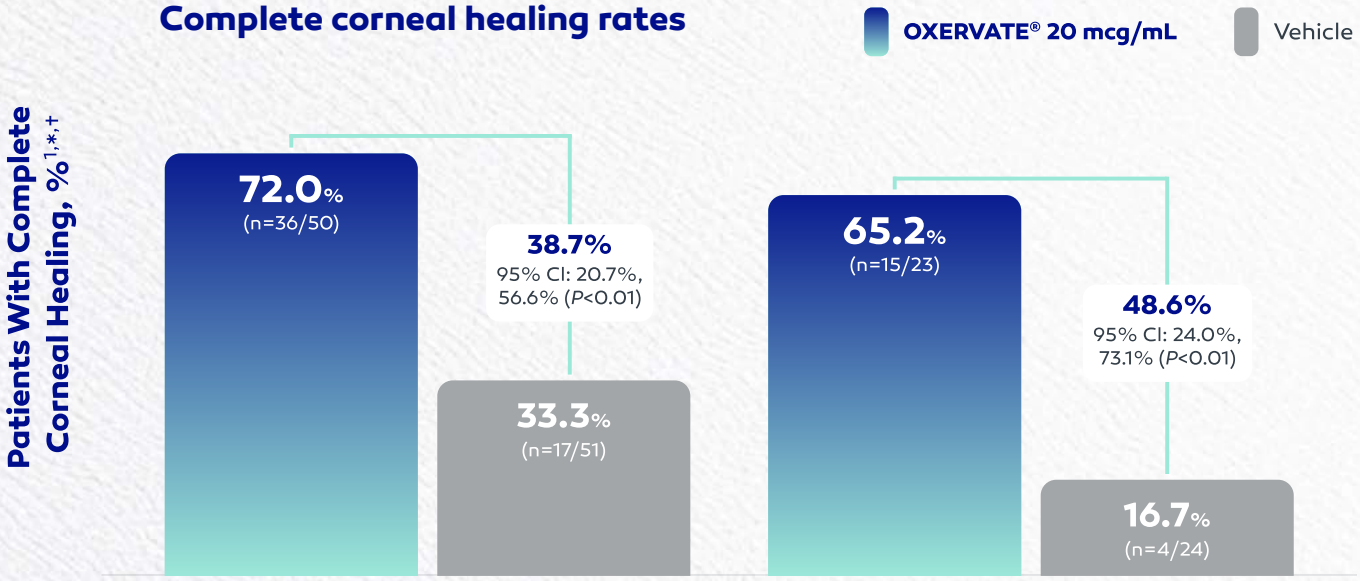
Please see additional Important Safety Information throughout and full Prescribing Information for OXERVATE.

Up to 72% of patients achieved complete corneal healing after one 8-week course of treatment[1,*]

The largest clinical trial program in patients with NK

The efficacy and safety of OXERVATE for the treatment of NK were studied in 151 patients, evaluated in two 8-week, randomized, multi-center, double-masked, vehicle-controlled studies.[1]

Complete corneal healing rates



In patients who were healed after 8 weeks of treatment, recurrences occurred in[1,5,6]:

NGF0212	NGF0214
~20% at 48 weeks	14% at 24 weeks

OXERVATE has a well-established safety profile[1]

- Eye pain was the most common adverse reaction, reported in ~16% of patients
  - Eye pain may arise as healing occurs
- Other adverse reactions occurring in 1% to 10% of patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation, photophobia, tearing, and headache

*Complete corneal healing was defined as the absence of staining of the corneal lesion and no persistent staining in the rest of the cornea at 8 weeks of treatment.[1]
†Patients without any post-baseline measurements were excluded from the analysis.[1]

Important Safety Information (cont'd)
USE IN SPECIFIC POPULATIONS (cont'd)

Lactation

The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for OXERVATE, and any potential adverse effects on the breastfed infant from OXERVATE.

Please see additional Important Safety Information throughout and full Prescribing Information for OXERVATE.

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Real-world patient outcomes with OXERVATE®



APPLY 1 DROP IN THE AFFECTED EYE(S)[1]

1 DROP 6x — 6 TIMES DAILY

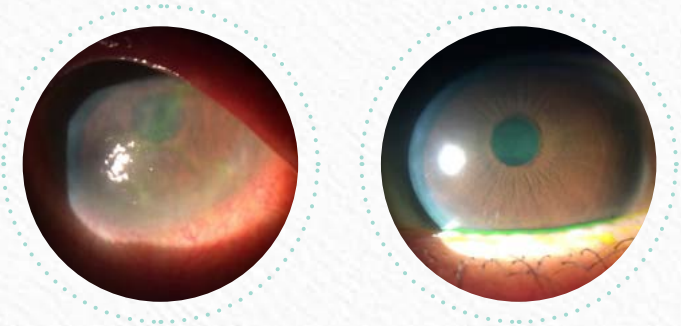
2 HRS — AT 2-HOUR INTERVALS

8 WEEKS — FOR 8 WEEKS

*OXERVATE can be **stored at room temperature** for up to 12 hours and up to 77 °F (25 °C) after being taken out of the refrigerator.*[1]

Baseline

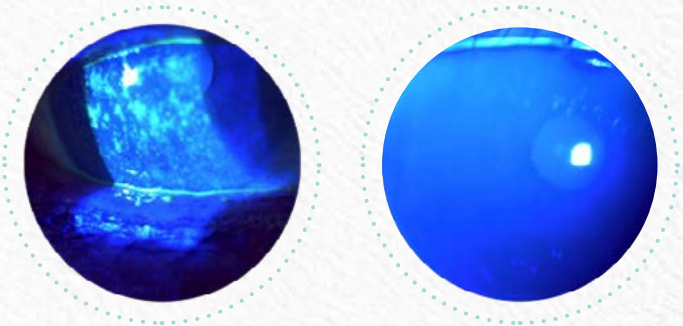
Week 8
Complete corneal healing*



Images provided by Ashraf Ahmad, MD.

Baseline

Week 8
Complete healing of persistent epithelial defects†



Images provided by Doug Devries, OD, FAAO.

*Based on a real-world patient assessment. Complete corneal healing was defined as the absence of staining of the corneal lesion and no persistent staining in the rest of the cornea at 8 weeks of treatment. Follow-up data past 8 weeks are not available; recurrence of persistent epithelial defect may have occurred.[3]

†Based on a real-world patient assessment. Complete healing of persistent epithelial defects was defined by absence of residual epithelial defect on fluorescein staining. Follow-up data past 8 weeks are not available; recurrence of persistent epithelial defect may have occurred.[3]

Click here to view more real-world patient cases

Important Safety Information (cont'd)

USE IN SPECIFIC POPULATIONS (cont'd)

Pediatric Use

The safety and effectiveness of OXERVATE have been established in the pediatric population. Use of OXERVATE in pediatric patients 2 years of age and older is supported by evidence from adequate and well-controlled trials of OXERVATE in adults with additional safety data in children.

DOSAGE AND ADMINISTRATION

Instill one drop of OXERVATE in the affected eye(s), 6 times a day at 2-hour intervals for eight weeks.

To report ADVERSE REACTIONS, contact Dompé U.S. Inc. at 1-833-366-7387 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for OXERVATE.

References: 1. OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) [US package insert]. San Mateo, CA: Dompé U.S. Inc.; 2024. **2.** Mastropasqua L et al. *J Cell Physiol.* 2017;232(4):717-724. **3.** Data on file. San Mateo, CA: Dompé U.S. Inc. **4.** Voelker R. *JAMA.* 2018;320(13):1309. **5.** Pflugfelder SC et al. *Ophthalmology.* 2020;127(1):14-26. **6.** Bonini S et al. *Ophthalmology.* 2018;125(9):1332-1343.

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