For the treatment of all stages of neurotrophic keratitis (NK)

NOT JUST ANY SOLUTION

A RESOLUTION

OXERVATE® is the only FDA-approved treatment option to enable complete corneal healing in most patients with NK.*[1-3]

OXERVATE may cause mild to moderate eye discomfort such as eye pain during treatment.[1]

*Resolution was evaluated in clinical trials as complete corneal healing, defined as the absence of staining in the lesion area and no persistent staining in the rest of the cornea after 8 weeks of treatment and as <0.5-mm lesion staining at 48-week follow-up.[1-3]

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.

Please see Important Safety Information throughout and on page 8, and full Prescribing Information for OXERVATE.

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

RESOLUTIONARY CARE

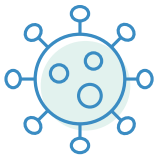
NK is caused by corneal nerve damage[4]

Corneal nerve damage may lead to a decrease in or total loss of corneal sensitivity—the hallmark of neurotrophic keratitis (NK). This impairment in corneal innervation and sensitivity can lead to epithelial breakdown in the cornea.[5]

Other signs and symptoms of NK can include[5]

- Dryness
- Reduced blinking
- Photophobia
- Blurry vision

Common etiologies of NK include[4-7]



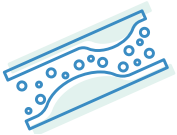
Post-herpetic infection

Diabetes

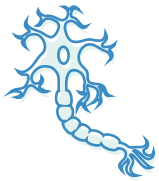
Contact lens wear

Topical ophthalmic drug toxicity (eg, glaucoma drops)

Chronic dry eye disease



Stroke



Multiple sclerosis

Ocular surgery (eg, LASIK, cataract surgery, corneal transplant, vitrectomy)

A patient with 1 or more of these symptoms, conditions, or etiologies should prompt suspicion of NK.[4-7]

Any injury or systemic condition affecting corneal sensory innervation can lead to NK[4]

Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (CONTINUED)

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 Important Safety Information throughout and on page 8, and full Prescribing Information for OXERVATE.

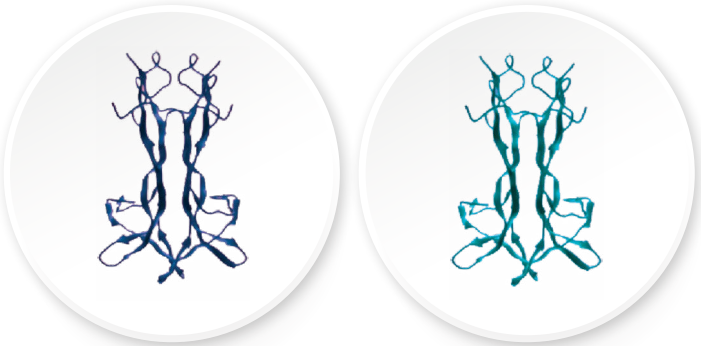
SEE MORE ETIOLOGIES >

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

A unique MOA that targets corneal nerve damage, the underlying cause of NK[1,4,8,9]

Cenegermin-bkbj, the active ingredient in OXERVATE®, is a recombinant form of human nerve growth factor (rhNGF)[1]

NGF is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity (ie, TrkA) and low-affinity (ie, p75NTR) nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity.[1]



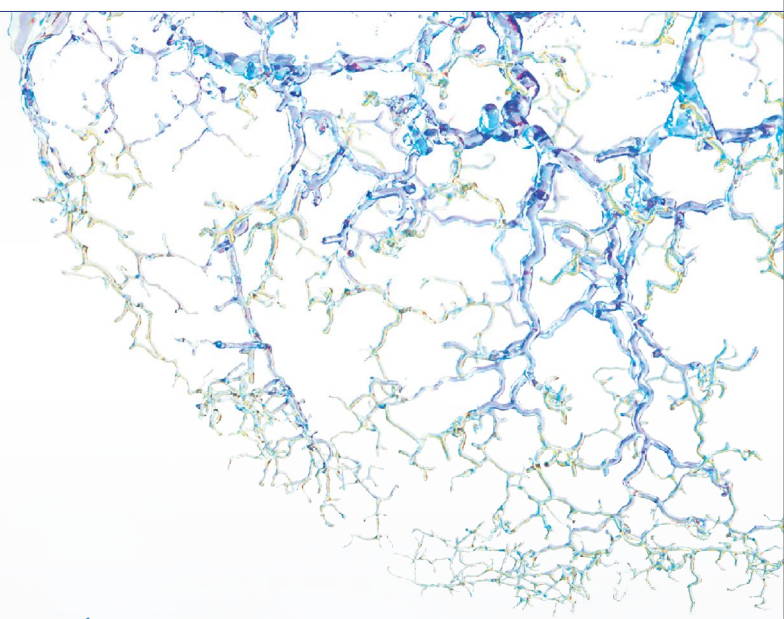
Cenegermin-bkbj | Endogenous NGF

Cenegermin-bkbj is structurally identical to human NGF protein made in ocular tissues.[10]

NGF and the ocular surface

Endogenous NGF supports corneal integrity through 3 mechanisms contributing to ocular surface homeostasis (shown in preclinical models)[1,4,11]:

- **Corneal innervation**
- **Tear secretion**
- **Epithelial cell growth**



Important Safety Information (continued)

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.

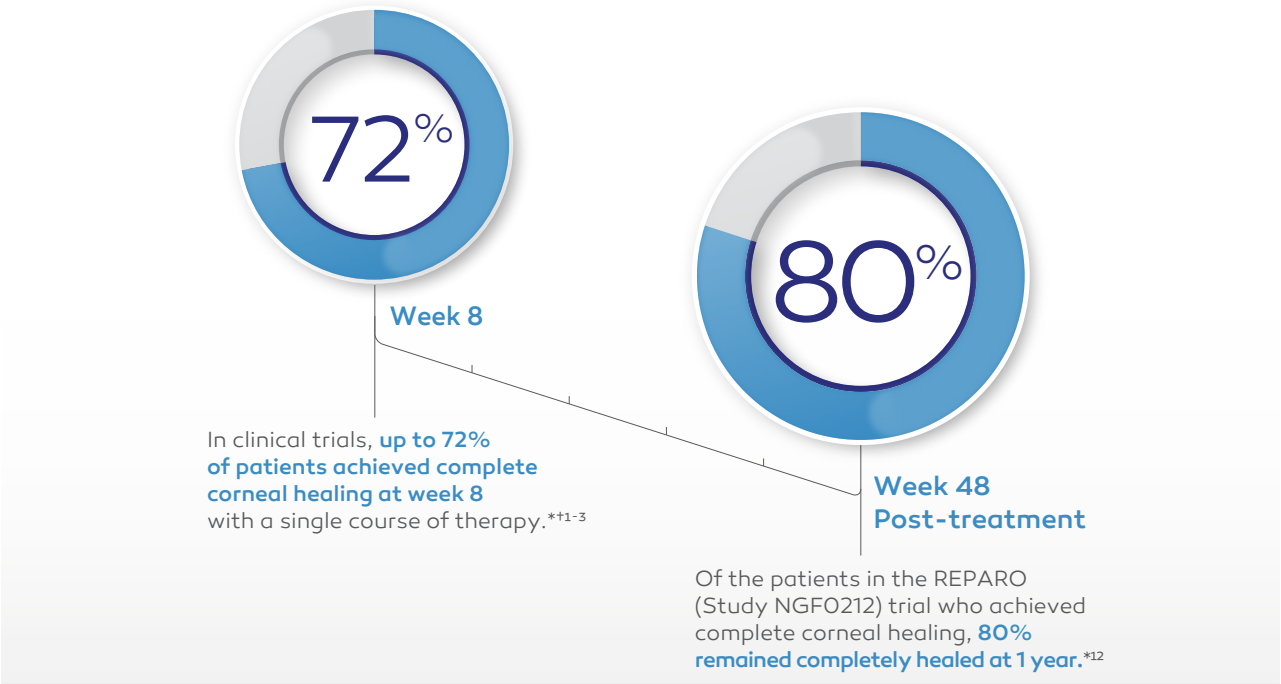
Please see Important Safety Information throughout and on page 8, and full Prescribing Information for OXERVATE.

SEE HOW NGF WORKS >

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

Complete and long-lasting resolution for most patients*[1-3,12]

OXERVATE® was studied in 2 independent, 8-week, randomized, multicenter, double-masked, vehicle-controlled clinical trials, REPARO (NGF0212) and NGF0214[1-3]



*Resolution was evaluated in clinical trials as complete corneal healing, defined as the absence of staining in the lesion area and no persistent staining in the rest of the cornea after 8 weeks of treatment and as <0.5-mm lesion staining at 48-week follow-up.[1-3]

†Key study findings were after 8 weeks of treatment, 6 times daily. REPARO (Study NGF0212): 52 patients with Stage 2 or 3 neurotrophic keratitis (NK) in 1 eye per group; 72% (36/50) of patients completely healed; vehicle response rate 33.3% (17/51). Study NGF0214: 24 patients with Stage 2 or 3 NK in 1 or both eyes per group; 65.2% (15/23) completely healed; vehicle response rate 16.7% (4/24). Last post-baseline observation carried forward; chi-squared test. Patients without any post-baseline measurements were excluded from the analysis.[1-3]

OXERVATE was generally well tolerated in clinical trials[2,3]

- 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[1]
- 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**[1]
- Most adverse events were local, mild, transient, and did not require treatment discontinuation[2,3]

Important Safety Information (continued)

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 Important Safety Information throughout and on page 8, and full Prescribing Information for OXERVATE.

EXPLORE EFFICACY & SAFETY >

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

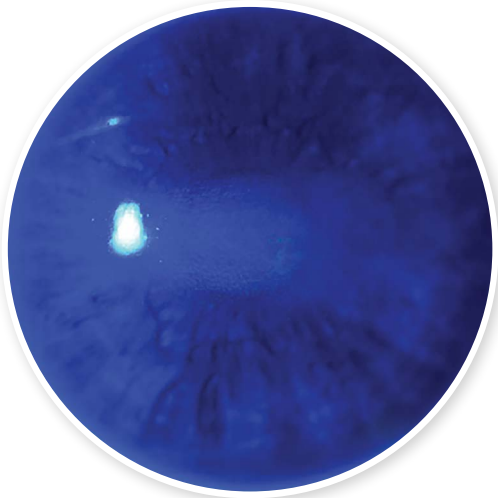
OXERVATE® works to resolve NK in most patients*[1-3,12]

Clinical outcomes

Images show a neurotrophic corneal lesion from baseline to week 8 in an actual patient treated with OXERVATE® in the REPARO trial. Results not indicative of all patients.

BASELINE

Stage 2 NK
History of herpes zoster and diabetes



WEEK 8

Complete corneal healing*

*Resolution was evaluated in clinical trials as complete corneal healing, defined as the absence of staining in the lesion area and no persistent staining in the rest of the cornea after 8 weeks of treatment and as <0.5-mm lesion staining at 48-week follow-up.[1-3]

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Important Safety Information (continued)

USE IN SPECIFIC POPULATIONS (CONTINUED)

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 Important Safety Information throughout and on page 8, and full Prescribing Information for OXERVATE.

REVIEW MORE CLINICAL DATA >

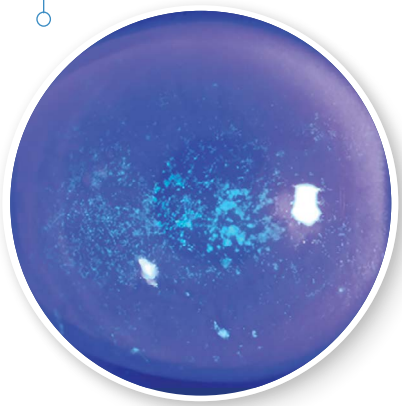
oxervate® (cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

FDA-approved for all stages of NK in patients 2 years of age and older[1]

Neurotrophic keratitis (NK) is a progressive disease and can present at any stage—early diagnosis is essential[5,6,11]

Stage 1*[5,13]

Punctate epithelial keratitis (PEK)
Surface epitheliopathy

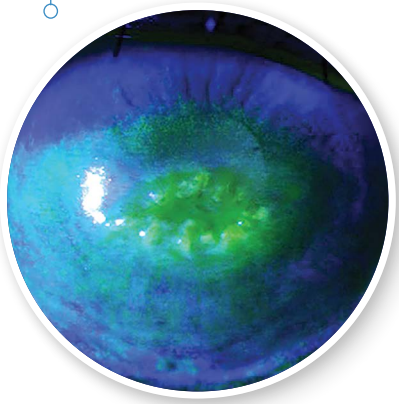


Stage 2*[5]

Persistent epithelial defect (PED)

Stage 3*[5]

Corneal ulcer



Since approval in 2018, more than 2000 total ophthalmologists and optometrists have prescribed OXERVATE®[14]

*Based on the Mackie classification.[5]

Important Safety Information (continued)

USE IN SPECIFIC POPULATIONS (CONTINUED)

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.

INDICATION

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

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LEARN THE STAGES OF NK >

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Access support and more through a single point of contact

Dompé | CONNECT *to* Care

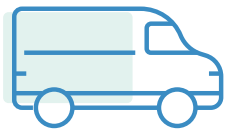
Providing practices *and* patients with assistance every step of the way

Program enrollment

Benefits verification

Prior authorizations

Patient financial assistance



Delivery coordination & confirmation

General questions

With Dompé copay support, a majority of patients with commercial insurance who were prescribed OXERVATE® paid no more than $100 out-of-pocket for an 8-week course of therapy[15]

Important Safety Information (continued)

DOSAGE AND ADMINISTRATION

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

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VIEW ALL ACCESS RESOURCES >

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

For patients with NK, it's time for Resolutionary Care

CONTACT A DOMPÉ REPRESENTATIVE >

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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.

References: 1. OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) [US package insert]. Boston, MA; Dompé U.S. Inc.; 2023. **2.** Bonini S, Lambiase A, Rama P, et al. Phase II randomized, double-masked, vehicle-controlled trial of recombinant human nerve growth factor for neurotrophic keratitis. *Ophthalmology*. 2018;125:1332-1343. **3.** Pflugfelder SC, Massaro-Giordano M, Perez VL, et al. Topical recombinant human nerve growth factor (cenegermin) for neurotrophic keratopathy: a multicenter randomized vehicle-controlled pivotal trial. *Ophthalmology*. 2020;127:14-26. **4.** Mastropasqua L, Massaro-Giordano G, Nubile M, Sacchetti M. Understanding the pathogenesis of neurotrophic keratitis: the role of corneal nerves. *J Cell Physiol*. 2017;232:717-724. **5.** Dua HS, Said DG, Messmer EM, et al. Neurotrophic keratopathy. *Prog Retin Eye Res*. 2018;66:107-131. **6.** Saad S, Abdelmassih Y, Saad R, et al. Neurotrophic keratitis: frequency, etiologies, clinical management and outcomes. *Ocul Surf*. 2020;18:231-236. **7.** Roth M, Dierse S, Alder J, Holtmann C, Geerling G. Incidence, prevalence, and outcome of moderate to severe neurotrophic keratopathy in a German tertiary referral center from 2013 to 2017. *Graefes Arch Clin Exp Ophthalmol*. 2022;260:1-13. **8.** Lambiase A, Sacchetti M, Bonini S. Nerve growth factor therapy for corneal disease. *Curr Opin Ophthalmol*. 2012;23:296-302. **9.** Ruiz-Lozano RE, Hernandez-Camarena JC, Loya-Garcia D, Merayo-Lloves J, Rodriguez-Garcia A. The molecular basis of neurotrophic keratopathy: Diagnostic and therapeutic implications. A review. *Ocul Surf*. 2021;19:224-240. **10.** Voelker R. New drug treats rare, debilitating neurotrophic keratitis. *JAMA*. 2018;320:1309. **11.** Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. *Clin Ophthalmol*. 2014;8:571-579. **12.** Data on File. Clinical Study Report (NGF0212). Dompé U.S. Inc., 2016. **13.** Versura P, Giannaccare G, Pellegrini M, Sebastiani S, Campos EC. Neurotrophic keratitis: current challenges and future prospects. *Eye Brain*. 2018;10:37-45. **14.** Data on File. Dompé U.S. Inc., 2022. **15.** Data on File. Dompé U.S. Inc., 2023.

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RESOLUTIONARY CARE

Dompé