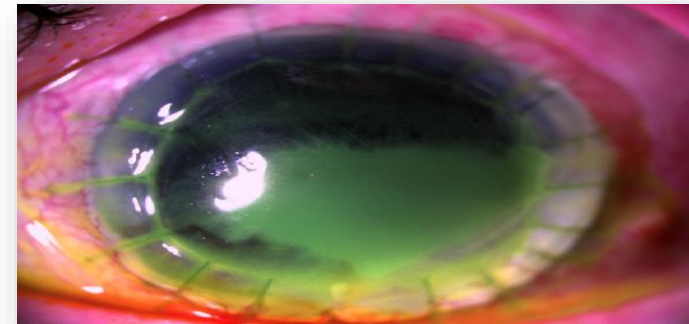


# US FDA approves OXERVATE (Cenegermin) first ever drug with an indication for management of Neurotrophic Keratitis (a rare disease affecting the cornea) on 22<sup>th</sup> Aug 2018



*Neurotrophic Keratitis (NK) is a degenerative disease of the cornea caused by damage of the trigeminal nerve, which results in impairment of corneal sensitivity, spontaneous corneal epithelium breakdown, poor corneal healing and development of corneal ulceration, melting and perforation.*

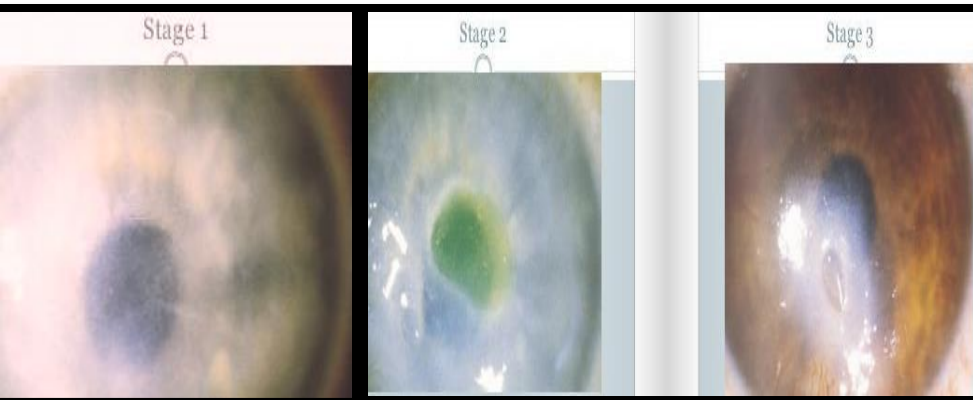
# Neurotrophic Keratitis Burden

## Neurotrophic Keratitis Signs & Symptoms

**Symptoms such as:** Burning, Foreign body sensation, Photophobia, and Dry eye.

➤ **Stage 1** Neurotrophic Keratitis (A) shows **cloudy** and irregular corneal epithelium associated with mild **stromal scarring**.

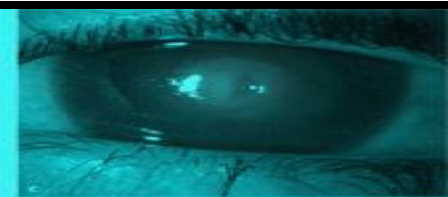
➤ **Stage 2** Neurotrophic Keratitis (B) with a large persistent epithelial defect characterized by smooth, rolled edges.



## Facts and Figures

The prevalence and incidence of NK may be estimated as being below 1.6/10,000 from the epidemiological data on conditions associated with NK, such as herpetic keratitis (1.22/10,000) and post-surgical procedures (0.02/10,000). In fact, NK develops in an average of 6% of herpetic keratitis cases, which have a prevalence of 149/100,000, and in 12.8% of herpes zoster keratitis cases, which have a prevalence of 26/100,000. In addition, 2.8% of patients who underwent surgical procedures for trigeminal neuralgia, developed NK. Given that the prevalence of trigeminal neuralgia is 1.5/10,000, the prevalence of NK for trigeminal neuralgia procedures can be estimated as 0.02/10,000. The percentage of NK cases caused by other conditions, such as diabetes, multiple sclerosis, acoustic neuroma, and congenital diseases, cannot be estimated because no data are available in the literature.

• Poorly functioning corneal nerves that result in secondary effects



# About OXERVATE (Cenegermin) (1)

## About the Dompe Farmaceutics

- Oxervate (Cenegermin) discovered by **Nobel Prize winner Rita Levi Montalcini**. It is a protein produced naturally by the human body that is responsible for the development, maintenance and survival of nerve cells.
- *Cenegermin was authorized by the European Medicines Agency (EMA) in 2017 and represents Dompé's first approved therapy in the United States, where it received Orphan Drug Designation, Fast Track Status, and Breakthrough Therapy Designation, which led to Priority Review.*
- Dompe Farmaceutici SpA operates as a holding company in the pharmaceutical industry based from Italy.
- Dompe will launch Oxervate in the U.S. by early 2019 and that the price has not yet been determined.



## Brief on Oxervate (Cenegermin)

- It is an ophthalmic solution for topical ophthalmic use.
- **INDICATIONS AND USAGE:** OXERVATE is a recombinant human nerve growth factor indicated for the treatment of Neurotrophic keratitis.
- **DOSAGE AND ADMINISTRATION:** One drop of OXERVATE in the affected eye(s), 6 times per day at 2-hour intervals, for eight weeks .



# About OXERVATE (Cenergermin) (2)

## Product information

### ➤ DOSAGE FORMS AND STRENGTHS:

Ophthalmic solution: cenergermin-bkbj 0.002% (20 mcg/mL) in a multiple-dose vial.

### ➤ CONTRAINDICATIONS: None.

### ➤ WARNINGS AND PRECAUTIONS:

Patients should remove contact lenses before applying OXERVATE and wait 15 minutes after instillation of the dose before reinsertion.

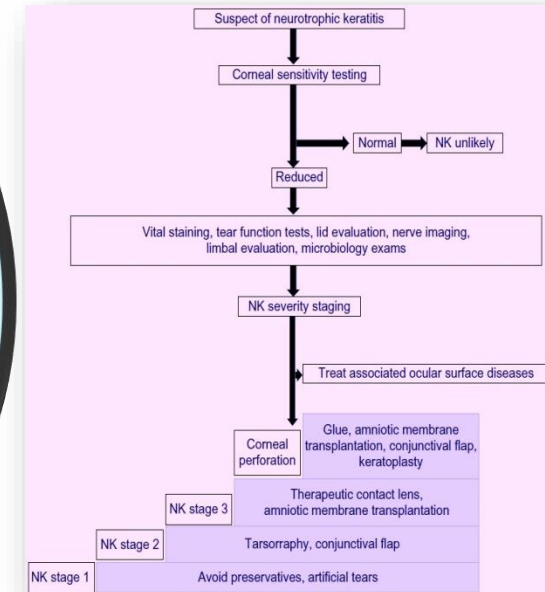
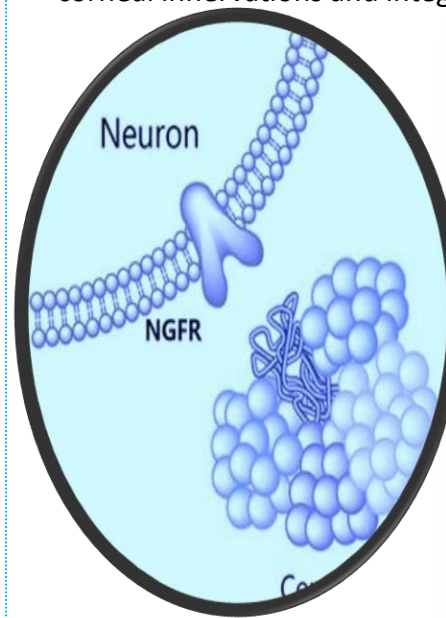
### ➤ ADVERSE REACTIONS:

The most common adverse reactions (incidence >5%) are: Eye pain, Ocular hyperemia, Eye inflammation and Increased lacrimation.

1 <sup>st</sup> stage	2 <sup>nd</sup> stage	3 <sup>rd</sup> stage
<ul style="list-style-type: none"> <li>• Superficial punctate keratopathy</li> <li>• Corneal epithelium hyperplasia or irregularity</li> <li>• Increase of viscosity of tear mucus</li> <li>• Neovascularization</li> <li>• Dellen</li> <li>• Stromal scarring</li> </ul>	<ul style="list-style-type: none"> <li>• Persistent corneal epithelial defects (PED)</li> <li>• Descemet's membrane folds and swelling of stroma</li> </ul>	<ul style="list-style-type: none"> <li>• Corneal ulcer</li> <li>• Corneal perforation</li> <li>• Corneal stromal melting</li> </ul>

## Mechanism of action

Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity (i.e., TrkA) and low-affinity (i.e. p75NTR) nerve growth factor receptors in the anterior segment of the eye to support corneal innervations and integrity.





# Market Overview - Neurotrophic Keratitis

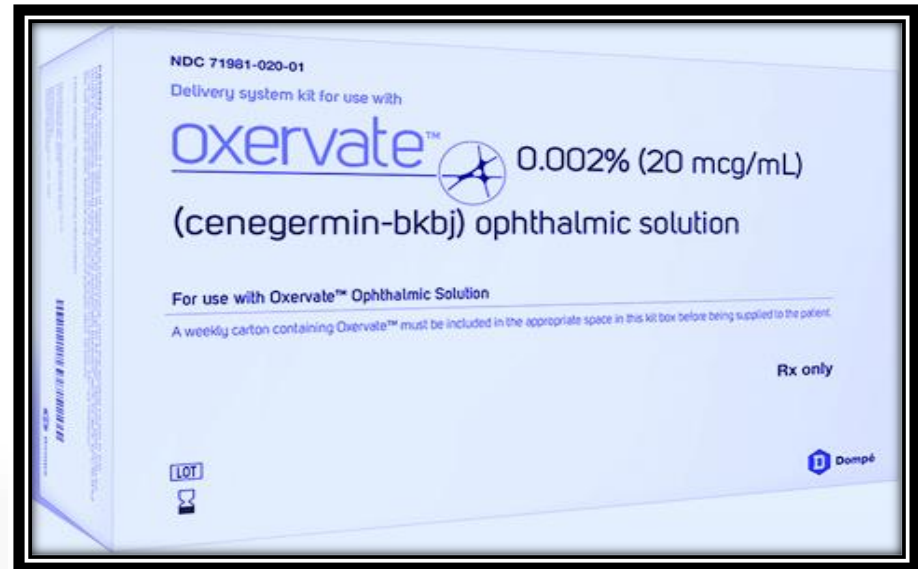
## Current Treatment options

- Stop all unnecessary medications
- Gentle debridement of boggy epithelium
- Artificial tears
- Mild steroid : If active stromal keratitis +nt
- Therapeutic soft CL
- Doxycycline 100mg PO once daily to inhibit collagenase
- Cycloplegics: if iritis is +nt
- Tarsorrhaphy
- Cyanoacrylate glue – if perforation occurs

## Top Competitive landscape for Oxervate

**Oxervate is the first drug permitted by the US FDA for the treatment of Neurotrophic keratitis, a rare disease affecting the cornea.**

oxervate 



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