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

YOU ARE CORDIALLY INVITED TO ATTEND A PRESENTATION

THE OXERVATE EXPERIENCE

Tuesday, October 6, 2020

Time: 7:00 pm EST
Click Here to Register for Zoom Meeting
Once registered you will receive a confirmation email from Zoom with the meeting link.

Presented By:
Paul Karpecki, O.D.
Associate Professor , University of Pikeville Kentucky College of Optometry
Director of Cornea Services, Kentucky Eye Institute
Lexington, KY

Hosted By:
Janice Perry
janice.perry@dompe.com
561-543-5643

Program Objectives:

1. To discuss neurotrophic keratitis (NK) and how it can be identified.
2. To present clinical data and information on OXERVATE (cenegermin-bkbj).

Registration

Register by one of the following methods
PHONE:
561-543-5643
janice.perry@dompe.com

Click Here to Register for Zoom Meeting

The information you provide will be used only to facilitate your attendance at the program. We look forward to your participation in this informative discussion. Program attendance is by invitation only, and we regret that this invitation cannot be forwarded.

Please see Important Safety Information on the following page.

Dompé

Important Safety Information

DOSAGE FORMS AND STRENGTHS
Ophthalmic solution: cenegermin-bkbj 0.002% (20 mcg/mL) in a multiple-dose vial

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

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:
Use with Contact Lens
Contact corrective lenses should be removed before applying OXERVATE™ because the presence of a contact lens (either therapeutic or e) 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.

USE IN SPECIFIC POPULATIONS:
Pregnancy: Risk Summary
There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks. Administration of cenegermin-bkbj to pregnant rats or rabbits during the period of organogenesis did not produce adverse fetal effects at clinically relevant doses. In a pre- and postnatal development study, administration of cenegermin-bkbj to pregnant rats throughout gestation and lactation did not produce adverse effects in offspring at clinically relevant doses.
Data: Animal Data
In embryofetal development studies, daily subcutaneous administration of cenegermin-bkbj to pregnant rats and rabbits throughout the period of organogenesis produced a slight increase in post implantation loss at doses greater than or equal to 42 mcg/kg/day (267 times the maximum recommended human ophthalmic dose [MRHOD]).
A no-observed-adverse-effect level (NOAEL) was not established for post implantation loss in either species. In rats, hydrocephaly and ureter anomalies were observed once each in fetuses at 267 mcg/kg/day (1709 times the MRHOD). In rabbits, cardiovascular malformations, including ventricular and atrial septal defects, enlarged heart, and aortic arch dilation, were observed once each in fetuses at 83 mcg/kg/day (534 times the MRHOD). No fetal malformations were observed in rats and rabbits at doses of 133 mcg/kg/day and 42 mcg/kg/day, respectively.
In a pre- and postnatal development study, daily subcutaneous administration of cenegermin-bkbj to pregnant rats during the period of organogenesis and lactation did not affect parturition and was not associated with adverse toxicity in offspring at doses up to 267 mcg/kg/day.
In parental rats and rabbits, an immunogenic response to cenegermin-bkbj was observed. Given that cenegermin-bkbj is a heterologous proteinin animals, this response may not be relevant to humans
Lactation: Risk Summary
There are no data on the presence of OXERVATE in human milk, the effects on breastfed infants, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OXERVATE and with any potential adverse effects on the breastfed infant.
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.
Geriatric Use
Of the total number of subjects in clinical studies of OXERVATE, 43.5% were 65 years old and older. No overall differences in safety or effectiveness were observed between elderly and younger adult patients.

Please see accompanying full Prescribing Information and Medication Guide.

The FDA-approved product labeling can be found at www.oxervate.com.
You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
You may also report side effects to Dompé at USDrugSafety@dompe.com.

©2019 Dompé Pharmaceuticals
All rights reserved
Dompé and the Dompé Logo are trademarks or registered trademarks of Dompé Pharmaceuticals
US-OXE-1900098 09/19

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

Dompé