Take a closer look at OXERVATE®

This brochure will help you understand why your doctor prescribed OXERVATE[®] and how to properly use it.

Not an actual patient.

Please see Important Safety Information throughout and on <u>page 18</u>, as well as the <u>full Prescribing Information</u>, including <u>Patient Information</u>.

What to know about your treatment with OXERVATE®:



Eye drops are applied with a specific device: After reading this brochure, be sure to talk with your doctor about how to properly prepare and use OXERVATE.

Please see Important Safety Information throughout and on <u>page 18</u>, as well as the <u>full Prescribing Information</u>, including <u>Patient Information</u>. Oxervate (cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

Using OXERVATE® Getting & Storing

Disease Information

About OXERVATE®

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Important Safety Information

What is OXERVATE?

• OXERVATE is a prescription eye drop solution used to treat a condition called neurotrophic keratitis.

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.

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NK and your cornea

Neurotrophic keratitis, also referred to as neurotrophic keratopathy, or "NK," is an eye disease caused by damage to the corneal nerves that leads to breakdown of the cornea. If not treated, it can lead to a corneal ulcer (an open sore in the cornea), scarring, or even vision loss.

NK is considered a rare disease and is estimated to affect approximately 70,000 people in the United States.*

*Based on the IRIS® Registry (Intelligent Research in Sight) data published in 2022 and adapted number based on the US population.

Important Safety Information (cont'd)

Before you use OXERVATE[®], tell your doctor about all of your medical conditions, including if you: (cont'd)

- 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.

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About OXERVATE

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Understanding your cornea & corneal nerves

The cornea is one of the most sensitive organs in the body. It acts as a covering for your eye, protecting your pupil and iris.



NK occurs when the nerves of the cornea are damaged

When your corneal nerves are damaged, your cornea has a lack of feeling and cannot send normal signals to your brain. This damage also prevents corneal nerves from providing nourishment to the corneal surface. As a result, the corneal surface can break down, which leads to NK.

Symptoms of NK may vary from person to person—some may not complain of symptoms at all, due to lack of feeling, while others may experience:



Talk to your doctor about what may have potentially caused the underlying nerve damage

Important Safety Information (cont'd)

How should I use OXERVATE®?

- 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.

Please see Important Safety Information throughout and on <u>page 18</u>, as well as the <u>full Prescribing Information</u>, including <u>Patient Information</u>.

OXervate (cenegermin-bk) Dompé farmaceuticis:

What is OXERVATE®?

The only prescription eye drop FDA-approved to treat people with neurotrophic keratitis (NK)

Important Safety Information (cont'd)

How should I use OXERVATE? (cont'd)

- 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.

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The active ingredient in OXERVATE® is cenegermin-bkbj

Cenegermin-bkbj is a manufactured protein that is identical to a protein your eye creates naturally. This protein is called nerve growth factor (NGF).



Cenegermin-bkbj manufactured



Nerve growth factor (NGF) made in your body

What does your body's NGF do?

In a healthy eye, NGF helps your cornea and corneal nerves stay healthy.



Important Safety Information (cont'd)

How should I use OXERVATE? (cont'd)

- **Do not** use other eye medicines without talking to your doctor.
- Talk to your doctor first before you stop using OXERVATE.

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.

Please see Important Safety Information throughout and on <u>page 18</u>, as well as the <u>full Prescribing Information</u>, including <u>Patient Information</u>.

Complete corneal healing for most people with NK

In the clinical trials, patients with NK were treated with OXERVATE[®] or placebo for 8 weeks



achieved complete corneal healing

Treatment success criteria at 8 weeks

After 8 weeks, each patients' degree of healing was determined by a doctor by staining the cornea. If there was no staining in the damaged part of the cornea, and no persistent staining in the rest of the cornea, the cornea was considered completely healed.



remained completely healed at 1 year

Treatment success criteria at 1 year

At a follow-up visit 48 weeks after the treatment period, patients in the REPARO trial who were completely healed were evaluated by a doctor again. If staining in the cornea was less than 0.5 mm in size, the cornea was considered to have remained completely healed.

Doctors use corneal staining to assess the amount of corneal tissue damage. The greater the amount of stain, the more tissue damage.

REPARO (Study NGF0212) included patients with NK in 1 eye:

- 72% of the 52 patients treated with OXERVATE and 33.3% of the 52 patients treated with placebo achieved complete corneal healing
- Patients had a follow-up visit 48 weeks after completing treatment

Study NGF0214 included patients with NK in 1 or both eyes:

- **65.2%** of the **24 patients treated with OXERVATE** and **16.7%** of the **24 patients treated with placebo** achieved complete corneal healing
- Patients had a follow-up visit 24 weeks after completing treatment

Important Safety Information (cont'd)

What are the possible side effects of OXERVATE?

 The most common side effect of OXERVATE is eye pain, enlarged blood vessels in the white of the eyes, swelling of the eye, and increase of tears.

Please see Important Safety Information throughout and on <u>page 18</u>, as well as the <u>full Prescribing Information</u>, including <u>Patient Information</u>. Oxervate[®] (cenegermin-bkbj ophthalmic solution) 0.002[%] (20 mcg/mL)

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Using OXERVATE®

Important Safety Information

OXERVATE® side effects

You may experience side effects while using OXERVATE®.

Before using OXERVATE:

• Tell your doctor if you have an infection in your eye. If you get an eye infection **while** using OXERVATE, talk to your doctor right away



While using OXERVATE:

- OXERVATE may cause mild to moderate eye discomfort such as eye pain during your treatment
- 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 patients in clinical trials have experienced when using OXERVATE:

- In clinical trials, most side effects reported by patients taking OXERVATE were mild and temporary
- The most common side effect was eye pain, reported by about 16% of patients
- Other side effects reported between 1% and 10% of patients treated with OXERVATE, and more frequently than patients treated with placebo, were corneal deposits, feeling of having something in the eye, enlarged blood vessels in the white of the eyes, swelling of the eye, and increase of tears

Ask your doctor what side effects you may experience when starting your treatment with OXERVATE The Doctor Discussion Guide on page 19 may help

Important Safety Information (cont'd)

What are the possible side effects of OXERVATE? (cont'd)

Tell your doctor if you have any side effects that bother you. These are not all the possible side effects of OXERVATE.

For more information about OXERVATE talk to your healthcare provider or pharmacist.



Using OXERVATE®

The way OXERVATE[®] is prepared and applied may be a change for you. This dosing and administration overview will help you understand how to use OXERVATE.

Not an actual patient.

It is extremely important that you use OXERVATE exactly as your doctor tells you and complete the full course of treatment for it to be effective.



Discussion Guide



Continue for 8 weeks

When getting ready to apply OXERVATE®, remember the: 15-minute rule

lf you:	Make sure to:		
Wear contact lenses in your affected eye(s)	Remove them before using OXERVATE and reinsert 15 minutes after using OXERVATE		
Use any other eye drops	Use other eye drops at least 15 minutes before or after using OXERVATE		
Use any other eye ointment, gel, or thick eye drop	Use OXERVATE first , then wait at least 15 minutes before using the other eye ointment gel, or drop		

If you miss a dose of OXERVATE, take your next dose at your scheduled time and **do not** take an extra dose to make up for the missed one.

Do not use other eye medicines without talking to your doctor.

Important Safety Information

What is OXERVATE?

• OXERVATE is a prescription eye drop solution used to treat a condition called neurotrophic keratitis.

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.



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A biweekly delivery of OXERVATE® includes everything you'll need for 2 weeks of administration: 2 weekly cartons, each with 7 multiple-dose vials of OXERVATE, and 2 Delivery System Kits, each with 7 days' worth of supplies. Patients with NK in both eyes will receive 4 weekly cartons and 4 Delivery System Kits.



Dose **Recording Card**

 Note the time you opened a new vial (when you connect the vial adapter to the vial during the week)

Important Safety Information (cont'd)

Before you use OXERVATE, tell your doctor about all of your medical conditions, including if you: (cont'd)

- 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.

How should I use OXERVATE?

- 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.

Please see Important Safety Information throughout and on page 18, as well as the full Prescribing Information, including Patient Information.



solution) 0.002% (20 mcg/mL)

An overview of applying OXERVATE®

These are not the complete administration instructions.



Refer to these resources for complete information on how to dose and administer OXERVATE

Watch the dosing & administration video <u>oxervate.com/watch</u> Read the complete Instructions for Use <u>oxervate.com/IFU</u>

Please see Important Safety Information throughout and on <u>page 18</u>, as well as the <u>full Prescribing Information</u>, including <u>Patient Information</u>. OXERVALE® (cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

Support every step of the way

Not an actual patient.

Two teams are dedicated to helping you access and afford OXERVATE[®] and answer questions you may have.

For more information on how Dompé CONNECT to Care and Accredo can support you through the fulfillment and treatment process, *turn to <u>page 16</u>*.



Discussion Guide

Dompé CONNECT to Care can help you access your OXERVATE® prescription:

When your doctor prescribes OXERVATE[®], you may also enroll in Dompé CONNECT to Care, a patient support program provided by the manufacturer of OXERVATE to help with:

- Insurance verification
- Financial assistance
- Prior authorizations
 General questions

Speak with a Dompé CONNECT to Care representative:

1-877-422-4412 Mon – Fri 8 AM – 8 PM ET

Accredo Health Group Inc.,

a specialty pharmacy,* manages deliveries of OXERVATE directly to you:

With OXERVATE, you don't go to the pharmacy every time you need a refill. Instead, Accredo ships OXERVATE to your home every 2 weeks, throughout your 8-week course of treatment.

In addition to coordinating your OXERVATE deliveries, an Accredo Pharmacist can also answer questions about dosing, administration, and what to expect during treatment.

*Unlike retail pharmacies, a specialty pharmacy only provides medications used to treat rare or complex diseases or conditions. Speak with an Accredo representative:

1-888-454-8860 24 hours a day, 7 days a week

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

The 5-step fulfillment process

Now that you're familiar with your support teams, let's look at how they'll guide you through your OXERVATE[®] experience:

When you elect to enroll in Dompé CONNECT to Care, you and your doctor will complete the enrollment form

 Within 24 hours, Dompé CONNECT to Care will call to confirm your insurance coverage, so be sure to have your insurance prescription card ready

Dompé CONNECT to Care calls about payment

• Once your insurance is verified, Dompé CONNECT to Care will call again to discuss financial assistance options



Scan the code to add Dompé CONNECT to Care to your contacts so you recognize the number

Accredo calls to coordinate shipment After financial assistance is approved, you

Step 3

Step 1

Step 2

 After financial assistance is approved, you must speak with an Accredo representative to provide your delivery address



Scan the code to add Accredo to your contacts so you recognize the number





Accredo delivers OXERVATE® to you

• Delivered every 2 weeks in a cooler packed with dry ice and weighs 22 pounds—use caution when handling

Treatment begins

- Congratulations! You're ready to get started
- The OXERVATE weekly cartons must be refrigerated within 5 hours of delivery
- Do not freeze

Storage guidelines:

Weekly cartons

- Keep in the refrigerator between 36°F to 46°F (2°C to 8°C)
- Keep for up to 14 days
- Keep vials in the weekly carton until required for use

Each daily vial

- Once opened (connecting the vial adapter to the vial), store vial in the refrigerator between 36°F to 46°F (2°C to 8°C) or at room temperature up to 77°F (25°C) for up to 12 hours
- Throw away used vial 12 hours after opening even if there is eye solution still left in the vial
- Keep all medicines out of the reach of children

If you need to start treatment right away after receiving the weekly carton, you must thaw the vial at room temperature, up to 77°F (25°C). This could take up to 30 minutes. **Do not shake the vial in an attempt to warm it up**



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Important Safety Information

What is OXERVATE?

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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 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.

How should I use OXERVATE?

- 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.
- Do not use other eye medicines without talking to your doctor.
- Talk to your doctor first before you stop using OXERVATE.

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 effect of OXERVATE is eye pain, enlarged blood vessels in the white of the eyes, swelling of the eye, and increase of tears.

Tell your doctor if you have any side effects that bother you. These are not all the possible side effects of OXERVATE.

For more information about OXERVATE talk to your healthcare provider or pharmacist.

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

Please see <u>full Prescribing Information</u>, including <u>Patient Information</u>.

Preparing for treatment

Get the conversation started

When you're prescribed OXERVATE[®] you might not know what to expect or feel uncertain about the process. Use these sample questions to help start a conversation with your doctor and get the information you need to feel confident using OXERVATE.

Not an actual patient.

Please see Important Safety Information throughout and on <u>page 18</u>, as well as the <u>full Prescribing Information</u>, including <u>Patient Information</u>.

Why was I prescribed OXERVATE®?

What is neurotrophic keratitis (NK)?

Where do I get OXERVATE?

Do I have to keep OXERVATE refrigerated at all times?

Important Safety Information

What is OXERVATE?

• OXERVATE is a prescription eye drop solution used to treat a condition called neurotrophic keratitis.

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.

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I've never used an eye dropper like this. How does it work?

What are the possible side effects of OXERVATE[®]?

What kind of eye pain might I experience?

When can I expect to see results?

Important Safety Information (cont'd)

Before you use OXERVATE, tell your doctor about all of your medical conditions, including if you: (cont'd)

- 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.

Please see Important Safety Information throughout and on page 18, as well as the full Prescribing Information, including Patient Information.



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Use this space to write down any other questions you think of or take notes when talking to your doctor.

Important Safety

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Information

Use this brochure to understand important details about your OXERVATE® treatment:



Complete corneal healing for most patients with neurotrophic keratitis (NK)* Refer to the About OXERVATE[®] section.



What are the possible side effects of OXERVATE?

- The most common side effect of OXERVATE is eye pain, enlarged blood vessels in the white of the eyes, swelling of the eye, and increase of tears
- Tell your doctor if you have any side effects that bother you. These are not all the possible side effects of OXERVATE



It's important to follow the full 8-week dosing schedule

 1 drop in the affected eye(s), every 2 hours, 6 times a day, over 8 weeks

For more information, go to OXERVATE.com

*In clinical trials, complete corneal healing was determined by a doctor as a patient having no staining (corneal tissue damage) in the damaged part of the cornea and no persistent staining in the rest of the cornea after the full 8 weeks of treatment.

Important Safety Information (cont'd)

How should I use OXERVATE?

- 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.

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