

OXERVATE® Patient Administration Video–Website version (US-OXE-2000150) Transcript

[00:00] (Calm music)

[00:16] This video explains how to apply OXERVATE (cenegermin-bkbj ophthalmic solution), an FDA-approved prescription eye drop.

[00:25] In this video we will go through five sections: Materials, Storage and Handling, Assembly, Preparation, Administration.

[00:35] Let's start off by reviewing the materials you will receive after your doctor prescribes OXERVATE.

[00:41] Read the Instructions for Use before you start using OXERVATE and each time you get a refill. There may be new information.

[00:49] This video does not take the place of talking to your doctor about your medical condition or your treatment. Only you and your doctor can decide if OXERVATE is right for you.

[00:59] Share the important information in this video with members of your household.

[01:04] OXERVATE is supplied in an insulated pack in weekly cartons containing seven multiple-dose vials. This may include either frozen and or refrigerated gel packs or in some cases dry ice.

[01:18] OXERVATE is supplied with an accompanying Delivery System Kit. The Delivery System Kit will have medical devices for withdrawing and using OXERVATE.

[01:27] You will receive both the OXERVATE weekly carton and the Delivery System Kit from the pharmacy.

[01:32] For each week of treatment per affected eye, you will receive one OXERVATE carton. One Delivery System Kit. Typically, your shipment will include a two-week supply of these materials.

[01:45] The OXERVATE carton contains seven multiple-dose vials of OXERVATE, one vial per day of the week.

[01:51] The Delivery System Kit contains seven vial adapters, 42 pipettes, 42 sterile disinfectant wipes, one dose recording card. One extra adapter, three extra pipettes, and three extra wipes are included as spares.

[02:07] Once you unpack OXERVATE, it is important to store and handle it properly.

[02:12] Remove the weekly carton or cartons of OXERVATE from the insulated pack and store it for up to 14 days in refrigerator in the original carton as soon as you can.

[02:22] Store the weekly carton at 36 to 46 degrees Fahrenheit (2 degrees Celsius to 8 degrees Celsius) no later than five hours from when you receive the medicine from your pharmacy. Do not freeze.

[02:35] OXERVATE is stored in a freezer at the pharmacy. If you start treatment right away after receiving the weekly carton, you will have to wait until the first vial is thawed.

[02:45] Thaw the vial at room temperature up to 77 degrees Fahrenheit (25 degrees Celsius).

[02:51] Thawing the vial could take up to 30 minutes when kept at room temperature.

[02:55] Keep all medicines out of the reach of children.

[02:59] Next, let's discuss how to assemble your multiple-dose vials of OXERVATE.

[03:04] Follow steps one through 19 each day you use OXERVATE.

[03:09] Gather your supplies. Remove one vial of OXERVATE from the refrigerator in the morning, always at the same time each morning to use during the day.

[03:19] If OXERVATE is to be used in both eyes, remove two vials from the refrigerator.

[03:25] From the Delivery System Kit, remove one vial adapter, one pipette, (if both eyes, two pipettes), one sterile disinfectant wipe, (if both eyes, two sterile disinfectant wipes), and dose recording card.

[03:41] Wash your hands.

[03:43] If you wear contact lenses, take them out before using OXERVATE.

[03:48] Remove the plastic flip-off cap from the vial. Peel off the back of the vial adapter blister pack.

[03:55] Without removing the vial adapter from its blister pack, connect it to the vial by firmly pushing it down until it snaps into place over the neck of the vial.

[04:04] The spike of the vial adapter should pierce through the vial's rubber stopper.

[04:09] After the vial adapter has been connected correctly, do not remove it from the vial.

[04:16] Note: after the vial adapter is connected to the vial, OXERVATE can be stored in the refrigerator between 36 to 46 degrees Fahrenheit (2 degrees Celsius to 8 degrees Celsius) for up to 12 hours.

[04:30] If needed, the OXERVATE with the connected vial adapter may be stored at room temperature up to 77 degrees Fahrenheit (25 degrees Celsius).

[04:40] Remove and throw away the packaging of the vial adapter.

[04:44] The multiple-dose vial of OXERVATE is now ready for use. One drop in the affected eye every two hours, six times a day.

[04:54] Now we'll go over how to prepare OXERVATE for administration. To withdraw and give each dose of OXERVATE, follow steps seven to 19.

[05:03] Take a single sterile disinfectant wipe and gently clean the surface of the valve on the connector part of the vial adapter.

[05:11] After cleaning, wait for about one minute to allow the valve to dry.

[05:16] Remove a pipette from its protective packaging. Screw the pipette clockwise into the connector part of the vial adapter.

[05:26] Make sure that the pipette plunger is pushed all the way down.

[05:30] Turn the vial upside down with the pipette still connected.

[05:35] Gently pull the plunger until it stops to draw the eye drop solution into the pipette. Make sure the plunger has reached the stop point.

[05:44] Check the pipette to make sure it contains the eye drop solution. Air bubbles may cause blockage and prevent the pipette from filling properly, especially the first time you withdraw the eye drop solution.

[05:56] If the pipette is empty, keep the vial with the connected pipette upside down. Push the plunger all the way in and pull it out again.

[06:05] After the pipette has been correctly filled, unscrew the pipette from the connector part of the vial adapter counterclockwise. Pull the pipette straight up to remove it.

[06:16] Next, we'll demonstrate how to administer OXERVATE to your affected eye.

[06:21] Sit or lie down to steady yourself when you instill OXERVATE.

[06:26] Holding the pipette pointing down between your middle finger and thumb, tilt your head back and position the pipette above your affected eye.

[06:35] With your other hand, hold down your lower eyelid, increasing the space between the inner eyelid and the eyeball. This space is called the conjunctival fornix.

[06:46] Gently push the plunger down until at least a drop is released into the conjunctival fornix. Make sure you do not touch your eye with the tip of the pipette.

[06:57] With your head still tilted back, blink a few times so that the medicine covers the surface of your eye.

[07:04] Throw away the used pipette right away after use, even if there's still some eye drop solution left in it. Only use one pipette for each eye and each dose.

[07:15] If you miss your eye and there is no longer any eye drop solution in the pipette, try again using a new pipette and wipe. Follow steps seven to 14.

[07:26] After each use throughout the day, place the vial back in the refrigerator or keep it below 77 degrees Fahrenheit (25 degrees Celsius) for the rest of the day with the vial adapter still connected.

[07:39] Repeat from step seven to step 16 every two hours, six times a day, using a new sterile disinfectant wipe and a new pipette each time.

[07:49] If you use drops in both eyes, repeat these instructions for your other eye using a new pipette. You will need to use two vials each day.

[07:58] Store the vial at or below 77 degrees Fahrenheit (25 degrees Celsius) throughout the day. You can also store the vial in the refrigerator, but do not freeze the vial.

[08:11] Throw away the used vial at the end of each day, even if there is still some eye drop solution left in it.

[08:16] Throw away the vial no later than 12 hours from the time you connected the vial adapter to it, even if there is eye solution left in the vial.

[08:25] Track each time you instill an eye drop of OXERVATE on the weekly dose recording card provided with the delivery system.

[08:32] This will allow you to track your six doses each treatment day, the date of the first use of the weekly supply, and the time of the vial opening, which is when you connect the vial adapter to the vial during the week.

[08:45] Reminders can be helpful. To make sure of accurate dosing every two hours, you may want to set an alarm on your phone or kitchen timer as a reminder for when to administer OXERVATE.

[08:57] Call your doctor for medical advice about side effects. You may report side effects to Dompé U.S. Incorporated at 1-833-366-7387 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

[09:19] For OXERVATE Instructions for Use, full Patient Information, and frequently asked questions, please visit www.oxervate.com.

[09:28] This video does not take the place of talking to your doctor about your medical condition or your treatment.

[09:35] Call us at 1-877-422-4412 to speak with Connect to Care representatives who are ready to help answer questions about OXERVATE, insurance coverage, and out-of-pocket costs.

[09:50] Consumer Important Safety Information

[09:53] What is OXERVATE?

[09:54] • OXERVATE is a prescription eye drop solution used to treat a condition called neurotrophic keratitis.

[10:00] Before you use OXERVATE, tell your doctor about all of your medical conditions, including if you:

[10:05] • have an infection in your eye. If you get an eye infection **while** using OXERVATE, talk to your doctor right away.

[10:10] • are pregnant or plan to become pregnant. It is not known if OXERVATE will harm your unborn baby.

[10:16] • 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.

[10:25] How should I use OXERVATE?

[10:28] • 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.

[10:38] • 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.

[10:46] • 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.

[10:56] • 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.

[11:05] • **Do not** use other eye medicines without talking to your doctor.

[11:08] • Talk to your doctor first before you stop using OXERVATE.

[11:12] **What should I avoid while using OXERVATE?**

[11:15] • 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.**

[11:22] **What are the possible side effects of OXERVATE?**

[11:25] • 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.

[11:33] Tell your doctor if you have any side effects that bother you. These are not all the possible side effects of OXERVATE.

[11:38] For more information about OXERVATE talk to your healthcare provider or pharmacist.

[11:43] **To report ADVERSE REACTIONS, contact Dompé U.S. Incorporated at 1-833-366-7387 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

[12:00] **Please see full Prescribing Information and Patient Information for OXERVATE.**