

INSTRUCTIONS FOR USE
OXERVATE® (ox'-er-vayt)
(cenegermin-bkbj)
ophthalmic solution, for topical ophthalmic use

Read this Instructions for Use before you start using OXERVATE® and each time you get a refill. There may be new information. This leaflet 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. Share the important information in this leaflet with members of your household.

Important:

- OXERVATE is for use in the eye.
- **Do not** shake the OXERVATE vial.
- Use OXERVATE with the vial adapters, sterile disinfectant wipes, and pipettes that come with your Delivery System Kit.

OXERVATE is supplied in an insulated pack, in weekly cartons containing 7 multiple-dose vials. OXERVATE is supplied with an accompanying Delivery System Kit. The Delivery System Kit will have medical devices for withdrawing and using OXERVATE. You will receive both the OXERVATE weekly carton(s) and the Delivery System Kit from the pharmacy.

The OXERVATE carton contains:

- 7 multiple-dose vials of OXERVATE (1 vial per day of the week)

The Delivery System Kit contains the following:

- 7 vial adapters
- 42 pipettes
- 42 sterile disinfectant wipes and
- Dose Recording Card (1)
- Extra adapter (1) pipettes (3) and wipes (3) are included as spares.

How should I store OXERVATE?

- Remove the weekly carton(s) of OXERVATE from the insulated pack and store it for up to 14 days in a refrigerator in the original carton as soon as you can.
- Store the weekly carton(s) at 36°F to 46°F (2°C to 8°C) **no later than 5 hours** from when you receive the medicine from your pharmacy. **Do not** freeze.
- 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. Thaw the vial at room temperature up to 77°F (25°C). Thawing the vial could take up to 30 minutes when kept at room temperature.
- **Keep all medicines out of the reach of children.**

Follow Steps 1 to 19 each day you use OXERVATE.

Gather your supplies:

- Remove 1 vial of OXERVATE from the refrigerator in the morning (always at the same time each morning) to use during the day. If OXERVATE is to be used in both eyes, remove 2 vials from the refrigerator
- 1 vial adapter
- 1 pipette (if both eyes 2 pipettes)
- 1 sterile disinfectant wipe (if both eyes 2 sterile disinfectant wipes)
- Dose Recording Card

Step 1. Wash your hands.

Step 2. If you wear contact lenses, take them out before using OXERVATE.

Step 3. Remove the plastic flip-off cap from the vial.



Step 4. Peel-off the back of the vial adapter blister pack.

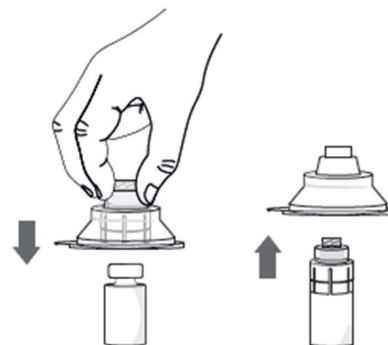


Step 5. Without removing the vial adapter from its blister pack, connect it to the vial by firmly pushing it down until it snaps into place over the neck of the vial. The spike of the vial adapter should pierce through the vial's rubber stopper. After the vial adapter has been connected correctly, do not remove it from the vial.

Note: After the vial adapter is connected to the vial, OXERVATE can be stored in the refrigerator between 36°F to 46°F (2°C to 8°C) for **up to 12 hours**.

If needed, the OXERVATE with the connected vial adapter may be stored at room temperature up to 77°F (25°C).

Step 6. Remove and throw away the packaging of the vial adapter.



The multiple-dose vial of OXERVATE is now ready for use (1 drop in the affected eye every 2 hours six times a day).

To withdraw and give each dose of OXERVATE, follow **Steps 7 to 19**:

Step 7. Take a single sterile disinfectant wipe and gently clean the surface of the valve on the connector part of the vial adapter.

After cleaning, wait for about 1 minute to allow the valve to dry.

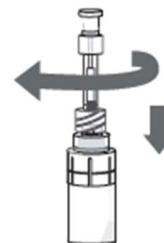


Step 8. Remove a pipette from its protective packaging.



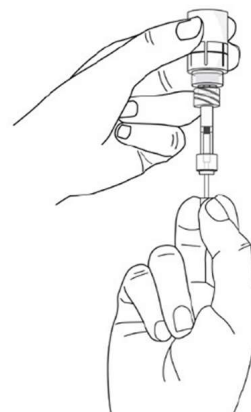
Step 9. Screw the pipette (clockwise) into the connector part of the vial adapter.

Step 10. Make sure that the pipette plunger is pushed all the way down.

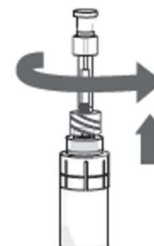


Step 11. Turn the vial upside-down with the pipette still connected. Gently pull the plunger until it stops, to draw the eye drop solution into the pipette. Make sure the plunger has reached the stop point.

Step 12. 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). 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.

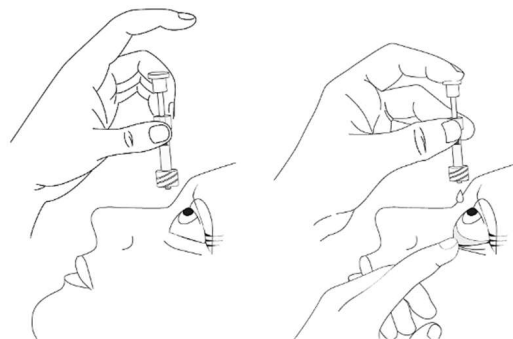


Step 13. After the pipette has been correctly filled, unscrew the pipette from the connector part of the vial adapter (counter-clockwise). Pull the pipette straight up to remove it.



Step 14.

- Sit or lie down to steady yourself when you instill OXERVATE.
- Holding the pipette, pointing down, between your middle finger and thumb, tilt your head back and position the pipette above your affected eye.
- With your other hand, pull down your lower eyelid, increasing the space between the inner eyelid and the eyeball (the conjunctival fornix).
- 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.
- With your head still tilted back, blink a few times so that the medicine covers the surface of your eye.



Step 15. Throw away the used pipette right away after use, even if there is still some eye drop solution left in it.

Only use 1 pipette for each eye and each dose.

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 (See **Steps 7 to 14**).

Step 16. After each use throughout the day, place the vial back in the refrigerator or keep it below 77°F (25°C) for the rest of the day, with the vial adapter still connected.



Step 17. Repeat from **Step 7** to **Step 16** every 2 hours 6 times a day, using a new sterile disinfectant wipe and a new pipette each time.

If you use drops in both eyes, repeat the above instructions for your other eye using a new pipette. You will need to use 2 vials each day.



Store the vial at or below 77°F (25°C) throughout the day. You can also store the vial in the refrigerator but do not freeze the vial.

Step 18. Throw away the used vial at the end of each day even if there is still some eye drop solution left in it. 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 still left in the vial.



Step 19. Track each time you instill an eye drop of OXERVATE on the weekly Dose Recording Card provided with the delivery system.

This will allow you to track your 6 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.

							
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To make sure accurate dosing every 2 hours, you may want to set an alarm as a reminder for dosing.

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

Manufactured by:
Dompé farmaceutici S.p.A.
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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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