

Patient Information
Xiidra™ (ZYE-druh)
(lifitegrast ophthalmic solution) 5%

What is Xiidra?

Xiidra is a prescription eye drop solution used to treat the signs and symptoms of dry eye disease. It is not known if Xiidra is safe and effective in children under 17 years of age.

Before you use Xiidra, tell your doctor if you:

- are using any other eye drops
- wear contact lenses
- are pregnant or plan to become pregnant. It is not known if Xiidra will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Xiidra passes into your breast milk. Talk to your doctor about the best way to feed your baby if you use Xiidra.

How should I use Xiidra?

See the complete Instructions for Use at the end of this Patient Information leaflet for detailed instructions about the right way to use Xiidra.

- Use Xiidra as your doctor tells you.
- Use 1 drop of Xiidra in each eye, 2 times each day, about 12 hours apart.
- Use Xiidra right away after opening. Throw away the single use container and any unused solution after you have applied the dose to both eyes. Do not save any unused Xiidra for later.

What are the possible side effects of Xiidra?

The most common side effects of Xiidra include eye irritation, discomfort, or blurred vision when the drops are applied to the eyes, and an unusual taste sensation (dysgeusia).

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Xiidra?

- Store Xiidra at room temperature between 68°F to 77°F (20°C to 25°C).
- Store Xiidra in the original foil pouch to protect it from light.
- Do not open the Xiidra foil pouch until you are ready to use the eye drops.
- Return unused single use containers to their original foil pouch to protect from excessive light exposure.

Keep Xiidra and all medicines out of the reach of children.

General information about the safe and effective use of Xiidra.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or doctor for information about Xiidra that is written for health professionals. Do not use Xiidra for a condition for which it was not prescribed. Do not give Xiidra to other people, even if they have the same symptoms you have. It may harm them.

What are the ingredients in Xiidra?

Active ingredient: lifitegrast

Inactive ingredients: sodium chloride, sodium phosphate dibasic anhydrous, sodium thiosulfate pentahydrate, sodium hydroxide and/or hydrochloric acid (to adjust pH) and water for injection.

**Manufactured for: Shire US Inc., 300 Shire Way,
Lexington, MA 02421**

**For more information, go to www.Xiidra.com or call
1-800-828-2088.**

**This Patient Information has been approved by the
U.S. Food and Drug Administration**

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**Instructions for Use
Xiidra™ (ZYE-druh)
(lifitegrast ophthalmic solution) 5%
for topical ophthalmic use**

Read this Instructions for Use before you start using Xiidra™ 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.

Important:

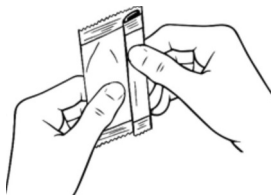
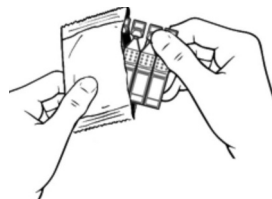
- Xiidra is for use in the eye.
- Wash your hands before each use to make sure you do not infect your eyes while using Xiidra
- If you wear contact lenses, remove them before using Xiidra.
- Xiidra single use containers are packaged in a foil pouch. Do not remove from the foil pouch until you are ready to use Xiidra.
- Do not let the tip of the Xiidra single use container touch your eye or any other surfaces.
- Use 1 drop of Xiidra in each eye 2 times each day (1 drop in the morning and 1 drop in the evening, approximately 12 hours apart). Each single use container of Xiidra will give you enough medicine to treat both of your eyes, 1 time. There is some extra Xiidra in each single use container in case you miss getting a drop into your eye. After you have applied the drops, throw away the single-use container and any unused Xiidra. Do not save any unused Xiidra.

Follow Steps 1 to 9 each time you use Xiidra:

Step 1. Take a foil pouch out of the Xiidra box. Open the pouch and remove the strip of single use containers. Pull off 1 single use container from the strip.



Step 2. Put the remaining strip of single use containers back in the pouch and fold the edge to close the pouch.



Step 3. Hold the Xiidra container upright. Make sure that the Xiidra solution is in the bottom part of the container.



Step 4. Open the Xiidra single use container by twisting off the tab. Make sure that the tip of the single use container does not touch anything, to avoid contamination.



Step 5. Tilt your head backwards. If you are not able to tilt your head, lie down.



Step 6. Gently pull your lower eyelid downwards and look up.

Step 7. Place the tip of the Xiidra single use container close to your eye, but be careful not to touch your eye with it.

Step 8. Gently squeeze the single use container and let 1 drop of Xiidra fall into the space between your lower eyelid and your eye. If a drop misses your eye, try again.

Step 9. Repeat steps 5-8 for your other eye. There is enough Xiidra in one single use container for both eyes.

Once you have applied a drop to both eyes, throw away the opened single use container with any remaining solution. If you use contact lenses, wait for at least 15 minutes before placing them back in your eyes.

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