



CHOOSE XIIDRA

Xiidra (Lifitegrast) 5% ophthalmic solution

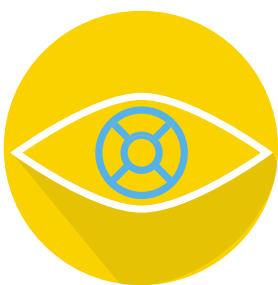


Xiidra is

FDA APPROVED
for the treatment of signs and symptoms of
DRY EYE DISEASE¹



Xiidra was studied in more than
2400 PATIENTS
in **5** clinical trials^{1,2}



Xiidra showed improvement in inferior
corneal staining

AT 12 WEEKS
In 3 out of 4 studies^{1,2}



Xiidra reduced symptoms of eye dryness

AT 2 WEEKS
in 2 out of 4 studies³,
with improvements observed
AT 6 & 12 WEEKS
in all 4 studies^{1,2,3}

**ACROSS THE FOUR 12-WEEK STUDIES, THE
RATES OF ADVERSE EVENTS LEADING TO
DISCONTINUATION WERE LOW AND THERE WAS NO
EVIDENCE OF INCREASED SYSTEMIC
ANOMALIES SUCH AS INFECTION⁴**

NEARLY **8 OUT OF 10**
XIIDRA-TREATED PATIENTS DID NOT USE
ARTIFICIAL TEARS AT DAY 90³

REFERENCES:

1. Xiidra [package insert]. Novartis Pharmaceuticals Corp. East Hanover, NJ; June 2020.
2. Australian Government. Australian Public Assessment Report for Lifitegrast. November 2019.
3. Holland EJ, et al. Ophthalmology. 2017;124:53-60.
4. Donnenfeld ED, Karpecki PM, Majmudar PA, et al. Safety of lifitegrast ophthalmic solution 5.0% in patients with dry eye disease: a 1-year, multicenter, randomized, placebo-controlled study. Cornea. 2016;35(6):741-748.

PATIENT INFORMATION

Xiidra®

(lifitegrast ophthalmic solution) 5% for topical ophthalmic use

What is Xiidra?

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

Do not use Xiidra:

- If you are allergic to lifitegrast or any of the other ingredients in Xiidra, see **"What are the ingredients in Xiidra?"**

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 one drop of Xiidra in each eye, two 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).

Seek medical care immediately if you get any symptoms of wheezing, difficulty breathing, or swollen tongue.

These are not all the possible side effects of Xiidra.

Tell your doctor if you have any side effects that bother you.

How should I store Xiidra?

- Store Xiidra below 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, and water for injection. Sodium hydroxide and/or hydrochloric acid (to adjust pH).

Pack sizes: 30 and 60 single-dose containers.

Not all pack sizes are marketed

Manufacturer

The Ritedose Corporation (TRC) 1 Technology Circle, Columbia, SC 29203, USA, For Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, NJ, United States of America.

This package leaflet was last revised in June 2020

® = registered trademark

This is a medicament

– A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

– Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

– The doctor and the pharmacist are experts in medicine, its benefits and risks.

– Do not by yourself interrupt the period of treatment prescribed for you.

– Do not repeat the same prescription without consulting your doctor.

INSTRUCTIONS FOR USE

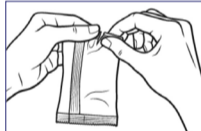

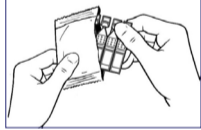


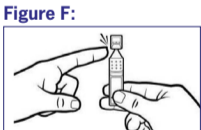

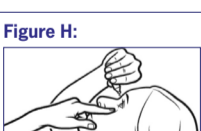
Xiidra® (lifitegrast ophthalmic solution) 5% for topical ophthalmic use

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 Information You Need to Know Before Using Xiidra:

- 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 one drop of Xiidra in each eye two times each day (one drop in the morning and one 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, one 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 this 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. (see Figure A)	Figure A: 
Pull off one single-use container from the strip. (see Figure B)	Figure B: 
Step 2. Put the remaining strip of single-use containers back in the pouch. (see Figure C)	Figure C: 
Fold the edge to close the pouch. (see Figure D)	Figure D: 
Step 3. Hold the Xiidra container upright. (see Figure E)	Figure E: 
Tap the top of the container until all of the solution is in the bottom part of the container. (see Figure F)	Figure F: 
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. (see Figure G)	Figure G: 
Step 5. Tilt your head backwards. If you are not able to tilt your head, lie down.	Figure H: 
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 one drop of Xiidra fall into the space between your lower eyelid and your eye. If a drop misses your eye, try again. (see Figure H)	
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.	

Keep medicaments out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists