

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**



Lifitegrast Ophthalmic Solution 5%

Read this carefully before you start taking XIIDRA[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about XIIDRA.

What is XIIDRA used for?

XIIDRA is an eye drop used to treat the signs and symptoms of dry eyes. Dry eyes occur when your eyes are not making enough tears or your tears are not normal.

How does XIIDRA work?

XIIDRA works by blocking the interaction between two types of proteins that can cause inflammation in dry eye disease.

It is important that you continue to use XIIDRA drops every day. Some patients may experience improvements in eye dryness symptoms in as early as 2 weeks.

What are the ingredients in XIIDRA?

Medicinal ingredient: Lifitegrast, 5% w/v

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

XIIDRA comes in the following dosage forms:

XIIDRA is a sterile, preservative-free, clear and colourless to slightly yellowish solution supplied in low density polyethylene single-use containers, packaged in foil pouches (5 single-use containers per pouch). Each single-use container contains 0.2 mL solution corresponding to 10 mg lifitegrast.

Each carton contains 12 pouches.

Do not use XIIDRA if:

You have an allergy to lifitegrast or any of the ingredients in XIIDRA. See **What are the ingredients in XIIDRA?**

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use XIIDRA. Talk about any health conditions or problems you may have, including if you:

- 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 whether or not XIIDRA is passed into breast milk.

Other warnings you should know about:

XIIDRA may cause your vision to blur temporarily when you put the drops in. If you experience blurred vision, wait until your vision clears before you try to drive or operate a machine.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XIIDRA:

There are no known drug interactions with lifitegrast.

How to use XIIDRA:

XIIDRA is for use in the eye only.

- The recommended dose is one drop into each eye – do this twice a day.

Before you use XIIDRA:

- Wash your hands before each use – this is to make sure you do not infect your eyes.
- If you wear contact lenses, remove them before using XIIDRA. You can put your lenses back in 15 minutes after you use XIIDRA.
- XIIDRA comes in single-use containers in a foil pouch. Do not remove the containers from the foil pouch until you are ready to use XIIDRA.
- Do not let the tip of the container touch your eye or any other surfaces - this is to prevent eye injuries and to help stop contamination.

About the single-use containers:

Each single-use container of XIIDRA contains enough for one dose in both of your eyes.

- There is some extra solution in each single-use container – this is in case you miss getting a drop into your eye.
- After you have used the drops, throw away the single-use container and any unused solution.
- Do not save any unused XIIDRA.

How to use:

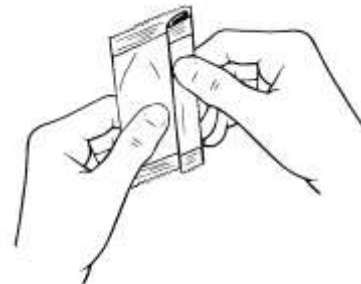
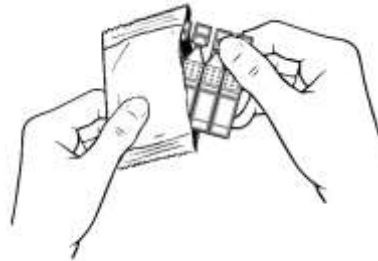
Step 1.

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



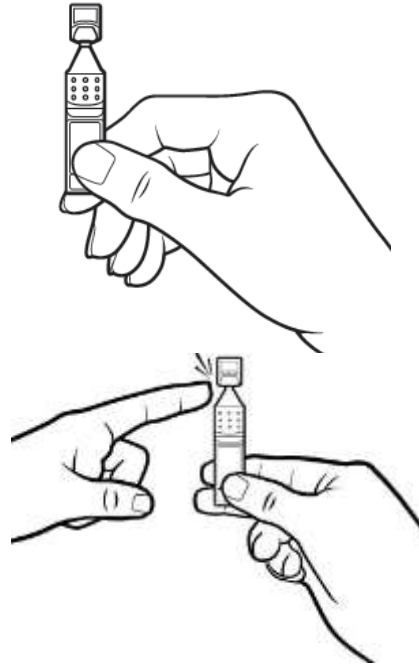
Step 2.

- Put the remaining strip of containers back in the pouch.
- Then fold the edge to close the pouch.



Step 3.


- Hold the container upright.
- Tap the top of the container until all of the solution is in the bottom part of the container.

**Step 4.**

- Twist off the tab to open the container.
- Make sure that the tip of the single-use container does not touch anything - this is to help stop contamination.

**Step 5.**

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

<p>Step 6.</p> <ul style="list-style-type: none"> • Gently pull your lower eyelid downwards - then look up. <p>Step 7.</p> <ul style="list-style-type: none"> • Place the tip of the container close to your eye - but be careful not to touch your eye with it. <p>Step 8.</p> <ul style="list-style-type: none"> • Gently squeeze the container • Let 1 drop fall into the space between your lower eyelid and your eye. • If a drop misses your eye, try again. 	
<p>Step 9.</p> <ul style="list-style-type: none"> • Repeat steps 5-8 for your other eye. • There is enough XIIDRA in one container for both eyes. <p>After use</p> <p>After you have applied a drop to both eyes, throw away the opened container - including any remaining solution.</p> <p>If you use contact lenses - wait for at least 15 minutes before placing them back in your eyes.</p>	

Usual dose:

Use 1 drop of XIIDRA in each eye, twice a day, about 12 hours apart.

Overdose:

If you think you have used too much XIIDRA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose of this medication, use it as soon as you remember. But if it is almost time

for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take two doses at the same time.

What are possible side effects from using XIIDRA?

These are not all the possible side effects you may feel when using XIIDRA. If you experience any side effects not listed here, contact your healthcare professional.

The very common side effects were:

- eye irritation, eye pain, eye reaction when drops are applied to the eyes
- unpleasant taste in the mouth

These effects occur when the drops are applied to the eyes.

Other common side effects are:

- blurred vision
- itchy eyes
- eye redness
- increase in tears
- headache
- sensitivity to light

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reactions: difficulty breathing or swallowing, swelling of tongue, lips and face, skin rash, itching and hives			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store XIIDRA between 15-30°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 container to their original foil pouch to protect from excessive light exposure
- Discard opened single-use container immediately after use

Keep out of reach and sight of children.

If you want more information about XIIDRA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://www.canada.ca/en/health-canada.html>, the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

XIIDRA is a registered trademark.

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