

PATIENT INFORMATION
ZIOPTAN™ (zye OP tan)
(tafluprost ophthalmic solution) 0.0015%

Read this Patient Information before you start using ZIOPTAN™ and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is ZIOPTAN?

ZIOPTAN is a prescription sterile eye drop solution. ZIOPTAN is used to lower the pressure in the eye (intraocular pressure) in people with open-angle glaucoma or ocular hypertension when their eye pressure is too high. ZIOPTAN belongs to a group of medicines called prostaglandin analogs.

ZIOPTAN is not for use in children.

What should I tell my doctor before using ZIOPTAN?

Before you use ZIOPTAN, tell your doctor if you:

- have or have had eye problems including any surgery on your eye or eyes
- are using any other eye medicines
- have any other medical problems
- are pregnant or plan to become pregnant. It is not known if ZIOPTAN will harm your unborn baby. You should use an effective method of birth control while you use ZIOPTAN. If you become pregnant while using ZIOPTAN talk to your doctor right away.
- are breastfeeding or plan to breastfeed. It is not known if ZIOPTAN passes into your breast milk. Talk to your doctor about the best way to feed your baby if you use ZIOPTAN.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take ZIOPTAN?

Read the Instructions for Use at the end of this Patient Information leaflet for additional instructions about the right way to use ZIOPTAN.

- **Use 1 drop of ZIOPTAN in your eye (or eyes) each evening.** Talk to your doctor or pharmacist if you are not sure how to use ZIOPTAN.
- Your ZIOPTAN may not work as well if you use it more than 1 time each evening.
- If you use other medicines in your eye, wait at least 5 minutes between using ZIOPTAN and your other eye medicines.
- Use your ZIOPTAN right away after opening. Each ZIOPTAN single-use container is sterile and is to be used 1 time then thrown away. Do not save any ZIOPTAN that may be left over after you use your medicine. Using ZIOPTAN that is not sterile may cause other eye problems.

What are the possible side effects of ZIOPTAN?

ZIOPTAN may cause serious side effects including:

- **changes in the color of your eye (iris).** Your iris may become more brown in color while using ZIOPTAN. This color change may not go away when you stop using ZIOPTAN. If ZIOPTAN is used in 1 eye only, the color of that eye may always be a different color from the color of your other eye.
- **darkening of the color of the skin around your eye (eyelid).** These skin changes usually go away when you stop using ZIOPTAN.
- **increasing the length, thickness, color, or number of your eyelashes.** These eyelash changes usually go away when you stop using ZIOPTAN.
- **hair growth on your eyelids.** This hair growth usually goes away when you stop using ZIOPTAN.

The most common side effects of ZIOPTAN include:

- redness, stinging or itching of your eye
- cataract formation
- dry eye
- eye pain
- blurred vision
- headache
- common cold
- cough
- urinary tract infection

Tell your doctor if you have any new eye problems while using ZIOPTAN including:

- an eye injury
- an eye infection
- a sudden loss of vision
- eye surgery
- swelling and redness of and around your eye (conjunctivitis)
- problems with your eyelids

Additionally, the following side effects have been reported in general use:

- worsening of asthma
- shortness of breath

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

These are not all the possible side effects of ZIOPTAN. For more information, ask your doctor or pharmacist.

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 ZIOPTAN?

Keep the foil pouches and ZIOPTAN single-use containers dry.

Before opening the foil pouches:

- Store the unopened foil pouches in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Do not open the pouch containing ZIOPTAN until you are ready to use the eye drops.

After opening the foil pouch:

- Store the opened foil pouch at room temperature, between 68°F to 77°F (20°C to 25°C), for up to 28 days.
- Throw away all unused ZIOPTAN single-use containers in the opened foil pouch after 28 days.
- Keep the ZIOPTAN single-use containers in their original foil pouch.
- After opening the foil pouch, refrigeration is not required.

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

General information about the safe and effective use of ZIOPTAN.

Do not use ZIOPTAN for a condition for which it was not prescribed. Do not give ZIOPTAN to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about ZIOPTAN. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about ZIOPTAN that is written for health professionals.

What are the ingredients in ZIOPTAN?

Active ingredients: tafluprost

Inactive ingredients: glycerol, sodium dihydrogen phosphate dihydrate, disodium edetate, and polysorbate 80, hydrochloric acid and/or sodium hydroxide, and water

Instructions for Use




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Important:

- **ZIOPTAN is for the eye only. Do not swallow ZIOPTAN.**
- ZIOPTAN single-use containers are packaged in a foil pouch.
- **Do not** use the ZIOPTAN single-use containers if the foil pouch is opened.
- Write down the date you open the foil pouch in the space provided on the pouch.

Every time you use ZIOPTAN:

Step 1. Wash your hands.	
Step 2. Take the strip of single-use containers	

<p>from the foil pouch.</p>	
<p>Step 3. Pull off one single-use container from the strip.</p>	
<p>Step 4. Put the remaining strip of single-use containers back in the foil pouch and fold the edge to close the pouch.</p>	
<p>Step 5. Hold the single-use container upright. Make sure that your ZIOPTAN medicine is in the bottom part of the single-use container. See Figure A.</p>	 <p>Figure A</p>
<p>Step 6. Open the single-use container by twisting off the tab. See Figure B.</p>	 <p>Figure B</p>
<p>Step 7. Tilt your head backwards. If you are unable to tilt your head, lie down.</p> <p>Step 8. Place the tip of the single-use container close to your eye. Be careful not to touch your eye with the tip of the single-use container. See Figure C.</p>	 <p>Figure C</p>

Step 9. Pull your lower eyelid downwards and look up.

Step 10. Gently squeeze the container and let 1 drop of ZIOPTAN fall into the space between your lower eyelid and your eye. If a drop misses your eye, try again.

See Figure D.



Figure D

- If your doctor has told you to use ZIOPTAN drops in both eyes, repeat Steps 7 to 10 for your other eye.
- There is enough ZIOPTAN in one single-use container for both of your eyes.
- **Throw away the opened single-use container with any remaining ZIOPTAN right away.**

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

Rx only

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