

## PATIENT INFORMATION

### ZIOPTAN® (zeye 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®?

##### Important information for Mail-Order Patients:

Do not use if prescription is not received within two days of dispensing date.

##### 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 30 days.
- Throw away all unused ZIOPTAN® single-use containers in the opened foil pouch after 30 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 for injection.

## Instructions for Use

Read these Instructions for Use before using your ZIOPTAN® and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

##### 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®:

<b>Step 1.</b> Wash your hands.	
<b>Step 2.</b> Take the strip of single-use containers from the foil pouch.	
<b>Step 3.</b> Pull off one single-use container from the strip.	
<b>Step 4.</b> Put the remaining strip of single-use containers back in the foil pouch and fold the edge to close the pouch.	
<b>Step 5.</b> Hold the single-use container upright. Make sure that your ZIOPTAN® medicine is in the bottom part of the single-use container. <b>See Figure A.</b>	 <b>Figure A</b>
<b>Step 6.</b> Open the single-use container by twisting off the tab. <b>See Figure B.</b>	 <b>Figure B</b>
<b>Step 7.</b> Tilt your head backwards. If you are unable to tilt your head, lie down.	
<b>Step 8.</b> 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. <b>See Figure C.</b>	 <b>Figure C</b>
<b>Step 9.</b> Pull your eyelid downwards and look up.	
<b>Step 10.</b> 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. <b>See Figure D.</b>	 <b>Figure D</b>

- 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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