ZIOPTAN- tafluprost solution/ drops
Thea Pharma Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ZIOPTAN ® (tafluprost ophthalmic solution) 0.0015% safely and effectively. See full prescribing information for ZIOPTAN ®.

ZIOPTAN ® (tafluprost ophthalmic solution) 0.0015%

Initial U.S. Approval: 2012

RECENT MAJOR CHANGES

ZIOPTAN is a prostaglandin analog indicated for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. (1)

RECENT MAJOR CHANGES

- Apply one drop in the affected eye(s) once daily in the evening. (2)

RECENT MAJOR CHANGES

- Pigmentation

Pigmentation of the iris, periorbital tissue (eyelid) and eyelashes can occur. Iris pigmentation is likely to be permanent. (5.1)

- Eyelash Changes

Gradual changes to eyelashes including increased length, thickness and number of lashes. Usually reversible. (5.2)

DOSAGE FORMS AND STRENGTHS

- Ophthalmic solution: 0.0015% tafluprost in a single-dose container. (3)

CONTRAINDICATIONS

- None. (4)

ADVERSE REACTIONS

Most common ocular adverse reaction is conjunctival hyperemia (4% to 20%). (6.1)
To report SUSPECTED ADVERSE REACTIONS, contact Thea Pharma Inc. at 1-833-838-4028 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- Use in pediatric patients is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use. (8.4)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.
Revised: 3/2026

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FULL PRESCRIBING INFORMATION

3 DOSAGE FORMS AND STRENGTHS

Ophthalmic solution: 0.0015% tafluprost in a single-dose container.

4 CONTRAINDICATIONS

None.

6 ADVERSE REACTIONS

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6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Preservative-containing or nonpreserved tafluprost 0.0015% was evaluated in 905 patients in five controlled clinical studies of up to 24-months duration. The most common adverse reaction observed in patients treated with tafluprost was conjunctival hyperemia which was reported in a range of 4% to 20% of patients. Approximately 1% of patients discontinued therapy due to ocular adverse reactions.

Ocular adverse reactions reported at an incidence of ≥ 2% in these clinical studies included ocular stinging/irritation (7%), ocular pruritus including allergic conjunctivitis (5%), cataract (3%), dry eye (3%), ocular pain (3%), eyelash darkening (2%), growth of eyelashes (2%) and vision blurred (2%).

Nonocular adverse reactions reported at an incidence of 2% to 6% in these clinical studies in patients treated with tafluprost 0.0015% were headache (6%), common cold (4%), cough (3%) and urinary tract infection (2%).

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of tafluprost. Because postapproval adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Respiratory disorders: exacerbation of asthma, dyspnea

Eye disorders: iritis/uveitis

In postmarketing use with prostaglandin analogs, periorbital and lid changes including deepening of the eyelid sulcus have been observed.

8 USE IN SPECIFIC POPULATIONS

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8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of ZIOPTAN administration in pregnant women to inform of drug-associated risks. In animal reproduction studies, intravenous administration of tafluprost to pregnant rabbits and rats throughout organogenesis resulted in embryofetal toxicities at exposures ≥5-times the human dose in rabbit and ≥2362-times the human dose in rat. (see Data).

The estimated background risk of major birth defects and miscarriage for the indicated population(s) is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4%

and 15 to 20%, respectively.

Data

Animal Data

In embryo-fetal development studies, intravenous administration of tafluprost to pregnant rats and rabbits during organogenesis caused increases in post-implantation losses in both species and reductions in fetal body weights in rats (≥0.03 mcg/kg/day in rabbits, 5-times the maximum clinical exposure based on Cmax; ≥10 mcg/kg/day in rats, 2362-times the maximum clinical exposure based on Cmax). Tafluprost also increased the incidence of vertebral skeletal abnormalities in rats and the incidence of skull, brain and spine malformations in rabbits at these same doses. In rats, there were no adverse effects on embryo-fetal development at a dose of 3 mcg/kg/day corresponding to maternal plasma levels of tafluprost acid that were 343 times the maximum clinical exposure based on Cmax. At the no-effect dose in rabbits (0.01 mcg/kg/day), maternal plasma levels of tafluprost acid were below the lower level of quantification (20 pg/mL).

In a pre- and postnatal development study, intravenous administration of tafluprost to pregnant rats during organogenesis and through birth and lactation, caused increased mortality of newborns, decreased body weights and delayed pinna unfolding in offsprings. The no observed adverse effect level was at a tafluprost intravenous dose of 0.3 mcg/kg/day which is greater than 3 times the maximum recommended clinical dose based on body surface area comparison.

8.2 Lactation

Risk Summary

There are no data on the presence of tafluprost or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production following topical ocular administration. Tafluprost and/or its metabolites are present in rat milk following ocular administration. When a drug is present in animal milk, it is likely that the drug will be present in human milk.

8.4 Pediatric Use

Use in pediatric patients is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

8.5 Geriatric Use

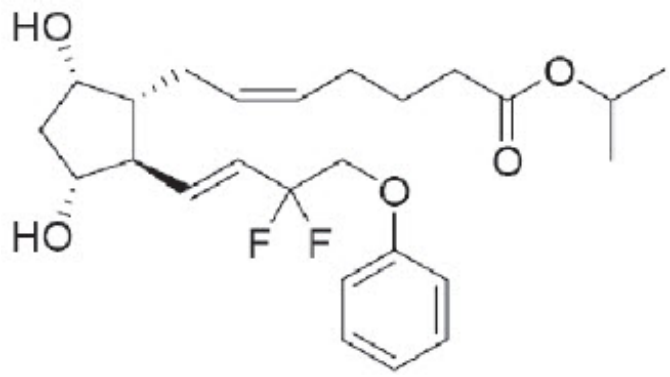
No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

11 DESCRIPTION

ZIOPTAN (tafluprost ophthalmic solution) 0.0015% contains tafluprost, a fluorinated analog of prostaglandin F2α, for topical ophthalmic use. The chemical name for tafluprost is 1-methylethyl (5Z)-7-{(1R,2R,3R,5S)-2-[(1E)-3,3-difluoro-4-phenoxy-1-butenyl}-3,5-dihydroxycyclopentyl]-5-heptenoate.

The molecular formula of tafluprost is $C_{25}H_{34}F_2O_5$ and its molecular weight is 452.53.

Its structural formula is:



Tafluprost is a colorless to light yellow viscous liquid that is practically insoluble in water.

ZIOPTAN is supplied as a sterile solution with a pH range of 5.5 to 6.7 and an Osmolality range of 260 to 300 mOsmo/kg.

ZIOPTAN contains Active: tafluprost 0.015 mg/mL; Inactives: disodium edetate, hydrochloric acid and/or sodium hydroxide (to adjust pH), glycerol, polysorbate 80, sodium dihydrogen phosphate dihydrate, and Water for Injection.

ZIOPTAN does not contain a preservative.

12 CLINICAL PHARMACOLOGY

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12.1 Mechanism of Action

Tafluprost acid, a prostaglandin analog is a selective FP prostanoid receptor agonist which is believed to reduce intraocular pressure by increasing uveoscleral outflow. The exact mechanism of action is unknown at this time.

12.3 Pharmacokinetics

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Absorption

Following instillation, tafluprost is absorbed through the cornea and is hydrolyzed to the biologically active acid metabolite, tafluprost acid. Following instillation of one drop of the 0.0015% solution once daily into each eye of healthy volunteers, the plasma concentrations of tafluprost acid peaked at a median time of 10 minutes on both Days 1 and 8. The mean plasma Cmax of tafluprost acid were 26 pg/mL and 27 pg/mL on Day 1, and Day 8, respectively. The mean plasma AUC estimates of tafluprost acid were 394 pg*min/mL and 432 pg*min/mL on day 1 and 8, respectively.

Elimination

Metabolism

Tafluprost, an ester prodrug, is hydrolyzed to its biologically active acid metabolite in the eye. The acid metabolite is further metabolized via fatty acid β-oxidation and phase II conjugation.

Mean plasma tafluprost acid concentrations were below the limit of quantification of the bioanalytical assay (10 pg/mL) at 30 minutes following topical ocular administration of tafluprost 0.0015% ophthalmic solution.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Tafluprost was not carcinogenic when administered subcutaneously daily for 24 months at doses up to 30 mcg/kg/day in rats and for 18 months at doses up to 100 mcg/kg/day in mice (over 1600 and 1300 times, respectively, the maximum clinical exposure based on plasma AUC).

Mutagenesis

Tafluprost was not mutagenic or clastogenic in a battery of genetic toxicology studies, including an in vitro microbial mutagenesis assay, an in vitro chromosomal aberration assay in Chinese hamster lung cells, and an in vivo mouse micronucleus assay in bone marrow.

Impairment of Fertility

In rats, no adverse effects on mating performance or fertility were observed with intravenous dosing of tafluprost at a dose of 100 mcg/kg/day (over 14000 times the maximum clinical exposure based on plasma Cmax or over 3600 times based on plasma AUC).

14 CLINICAL STUDIES

In clinical studies up to 24 months in duration, patients with open-angle glaucoma or ocular hypertension and baseline pressure of 23 to 26 mmHg who were treated with ZIOPTAN dosed once daily in the evening demonstrated reductions in intraocular pressure at 3 and 6 months of 6 to 8 mmHg and 5 to 8 mmHg, respectively.

16 HOW SUPPLIED/STORAGE AND HANDLING

ZIOPTAN (tafluprost ophthalmic solution) 0.0015% is supplied as a sterile solution in translucent low density polyethylene single-dose containers packaged in foil pouches (10 single-dose containers per pouch). Each single-dose container has 0.3 mL solution corresponding to 0.0045 mg tafluprost.

NDC 82584-609-30; Unit-of-Use Carton of 30.

Storage:

Store refrigerated at 2° to 8°C (36° to 46°F). During shipment ZIOPTAN may be maintained at temperatures up to 40°C (104°F) for a period not exceeding 2 days. Mail-order prescriptions received after two days of the dispensing date noted in the prescribing label should not be used. Store in the original pouch. After the pouch is opened, unopened single-dose containers may be stored in the opened foil pouch for up to 30 days at room temperature 20° to 25°C (68° to 77°F). Protect from moisture.

Write down the date you open the foil pouch in the space provided on the pouch. Discard any unopened containers 30 days after first opening the pouch.

17 PATIENT COUNSELING INFORMATION

Advise patients to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Potential for Pigmentation

Advise patients about the potential for increased brown pigmentation of the iris, which may be permanent. Also inform patients about the possibility of eyelid skin darkening, which may be reversible after discontinuation of ZIOPTAN.

Potential for Eyelash Changes

Inform patients of the possibility of eyelash and vellus hair changes in the treated eye during treatment with ZIOPTAN. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

Once Nightly Application

Advise patients to not exceed once daily dosing since more frequent administration may decrease the intraocular pressure lowering effect of ZIOPTAN.

Handling the Single-Dose Container

Advise patients that ZIOPTAN is a sterile solution that does not contain a preservative. The solution from one single-dose container is to be used immediately after opening for administration to one or both eyes. Since sterility cannot be maintained after the single-dose container is opened, discard the open container and remaining contents immediately after administration. Open a new single-dose container every time you use ZIOPTAN.

When to Seek Physician Advice

Advise patients that if they develop a new ocular condition (e.g., trauma or infection), experience a sudden decrease in visual acuity, have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice concerning the continued use of ZIOPTAN.

Use with Other Ophthalmic Drugs

Advise patients if more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.

Storage Information

Instruct patients on proper storage of cartons, unopened foil pouches, and opened foil pouches *[see How Supplied/Storage and Handling (16)].*

ecommended storage for cartons and unopened foil pouches is to store refrigerated at 2° to 8°C (36° to 46°F). After the pouch is opened, the single-dose containers may be stored in the opened foil pouch for up to 30 days at room temperature 20° to 25°C (68° to 77°F). Protect from moisture.

Manufactured for : **Thea Pharma Inc.**

Waltham, MA 02451

Made in France

U.S. Patent Nos. 9,999,593 and 10,864,159 and patent application US20210059931.

PATIENT INFORMATION

ZIOPTAN ® (zye OP tan)
(tafluprost ophthalmic solution) 0.0015% for topical ophthalmic use

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 helthcare provider about your medical condition or your treatment.

What is ZIOPTAN?

ZIOPTAN is a prescription eye drop solution 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 recommended for use in children.

Before using ZIOPTAN, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had eye problems including any surgery on your eye or eyes.
- are using any other eye medicines.
- are pregnant or plan to become pregnant. It is not known if ZIOPTAN will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZIOPTAN passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use ZIOPTAN.

Tell your healthcare provider 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 healthcare provider and pharmacist when you get a new medicine.

How should I use 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 affected eye or eyes each evening.** Talk to your healthcare provider 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.
- Contact lenses should be taken out before using ZIOPTAN and you should wait at least 15 minutes after giving the dose of ZIOPTAN before putting the contact lenses back into your eyes.
- Use your ZIOPTAN right away after opening for use in 1 or both eyes. Each ZIOPTAN single-dose 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, shape and 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.
- **inner eye swelling (inflammation).** Swelling or thickening may occur in the center of your eye (macular edema) and swelling in the middle layer of your eye (uveitis, intraocular inflammation) while using ZIOPTAN. Tell your healthcare provider if you experience eye inflammation or have a known risk of macular edema.

The most common side effects of ZIOPTAN include:

- redness, stinging or itching of your eye (conjunctival hyperemia or allergic conjunctivitis)
- cataract formation
- dry eye
- eye pain
- blurred vision
- headache
- common cold
- cough
- urinary tract infection

Tell your healthcare provider right away 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

Tell your healthcare provider 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 healthcare provider 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 ZIOPTAN if the prescription is not received within 2 days of the pharmacy filling (dispensing) date located on the prescription label.

Keep the foil pouches and ZIOPTAN single-dose 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:
- Write down the date of first opening the foil pouch in the space provided on the 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-dose containers in the opened foil pouch after 30 days.
- Keep the ZIOPTAN single-dose 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.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. 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 healthcare provider. You can ask your pharmacist or healthcare provider 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, polysorbate 80, hydrochloric acid and sodium hydroxide, and water for injection.

Instructions for Use

ZIOPTAN® (zye OP tan)
(tafluprost ophthalmic solution) 0.0015%
for topical ophthalmic 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 healthcare provider about your medical condition or your treatment.

Important Information You Need to Know Before Using ZIOPTAN:

- **ZIOPTAN is for the eye. Do not swallow ZIOPTAN.**
- ZIOPTAN single-dose containers are packaged in a foil pouch.
- Do not use the ZIOPTAN single-dose containers if the foil pouch is already opened when you receive it.
- Write down the date you open the foil pouch in the space provided on the pouch.
- **Use 1 drop of ZIOPTAN in your affected eye or eyes each evening.**
- If you use other eye medicines dropped into the eye (topically applied ophthalmic medicines), use each medicine at least 5 minutes apart from each other.

Follow these instructions every time you use ZIOPTAN:

Step 1.	Wash your hands and sit or stand comfortably.	
Step 2.	• Open the foil pouch containing a strip of 10 single-dose containers. • Write down the date of first opening on the foil pouch.	
Step 3.	• Take the strip of single-dose containers from the foil pouch. • Break off 1 single-dose container from the strip. • Put the remaining strip of unopened single-dose containers back in the foil pouch and fold the edge to close the pouch.	

Step 4. • Hold the single-dose container upright. • Make sure that your ZIOPTAN medicine is in the bottom part of the single-dose container. **See Figure A**.	 **Figure A**
Step 5. • Twist open the top of the single-dose container as shown. • Do not touch the tip after opening the container. **See Figure B**.	 **Figure B**
Step 6. Tilt your head backwards. If you are unable to tilt your head, lie down. **Step 7**. • Use your finger to gently pull down the lower eyelid of your affected eye and look up. • Place the tip of the single-dose container close to your eye, but not touching your eye.	

Step 8.	• Gently squeeze the single-dose container and let 1 drop of ZIOPTAN fall into the space between your lower eyelid and your eye, the release the lower eyelid. • If a drop misses your eye, try again. **See Figure C**.	 **Figure C**

- If your healthcare provider has told you to use ZIOPTAN drops in both eyes, repeat Steps 6 through 8 for your other eye.
- There is enough ZIOPTAN in 1 single-dose container for both of your eyes.
- **Throw away the opened single-dose container with any remaining ZIOPTAN right away. Do not keep it to use it again even if there is product left in the container.** To lessen the chance of infection, a new single-dose container must be opened each time you are ready to use ZIOPTAN.
- Place the folded foil pouch back in the carton. The unopened single-dose containers must be used within 30 days after opening the foil pouch. Protect from moisture.

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

Revised: 2/2026

Rx only

Manufactured for : **Thea Pharma Inc.**

Waltham, MA 02451

Made in France

PRINCIPAL DISPLAY PANEL - 0.3 mL Container Pouch Carton

NDC 82584-609-30

ZIOPTAN ®

(tafluprost ophthalmic

solution)

0.0015%

For Topical Application in the Eye

REFRIGERATE (2° to 8°C or 36° to 46°F)

Single-use Containers

Preservative-Free, Sterile

Contains:

Active: Tafluprost 0.0015%

(4.5 mcg per single-use container)

Inactive ingredients: Glycerol, Sodium Dihydrogen

Phosphate Dihydrate, Disodium Edetate, Polysorbate 80,

Water for Injection, Hydrochloric Acid and/or Sodium

Hydroxide are added to adjust pH.

Rx only

30 Single-use Containers:

3 pouches x 10 single-use containers

(0.3 mL each)

ZIOPTAN

tafluprost solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:82584-609
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TAFLUPROST (UNII: 1O6WQ6T7G3) (TAFLUPROST - UNII:1O6WQ6T7G3)	TAFLUPROST	0.015 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:82584-609-30	3 in 1 CARTON	10/28/2022	
1	NDC:82584-609-01	10 in 1 POUCH		
1		0.3 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	NDA202514	10/28/2022	

Labeler - Thea Pharma Inc. (117787029)

Revised: 3/2026 Thea Pharma Inc.