

AZASITE- azithromycin monohydrate solution/ drops
Thea Pharma Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AzaSite safely and effectively. See full prescribing information for AzaSite.

AzaSite[®] (azithromycin ophthalmic solution) 1%

Sterile topical ophthalmic drops

Initial U.S. Approval: 2007

INDICATIONS AND USAGE

AzaSite is a macrolide antibiotic indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following microorganisms: CDC coryneform group G, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus mitis* group, and *Streptococcus pneumoniae*. (1)

DOSAGE AND ADMINISTRATION

Instill 1 drop in the affected eye(s) twice daily, eight to twelve hours apart for the first two days and then instill 1 drop in the affected eye(s) once daily for the next five days. (2)

DOSAGE FORMS AND STRENGTHS

2.5 mL of 1% sterile topical ophthalmic solution. (3)

CONTRAINDICATIONS

Hypersensitivity (4)

WARNINGS AND PRECAUTIONS

- For topical ophthalmic use only. (5.1)
- Anaphylaxis and hypersensitivity have been reported with systemic use of azithromycin. (5.2)
- Growth of resistant organisms may occur with prolonged use. (5.3)
- Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis. (5.4)

ADVERSE REACTIONS

Most common adverse reaction reported in patients was eye irritation (1-2% of patients). (6)

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.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 5/2022

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AzaSite[®] is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following microorganisms:

CDC coryneform group G¹
Haemophilus influenzae
Staphylococcus aureus
Streptococcus mitis group
Streptococcus pneumoniae

1 Efficacy for this organism was studied in fewer than 10 infections.

2 DOSAGE AND ADMINISTRATION

The recommended dosage regimen for the treatment of bacterial conjunctivitis is:

Instill 1 drop in the affected eye(s) twice daily, eight to twelve hours apart for the first two days and then instill 1 drop in the affected eye(s) once daily for the next five days.

3 DOSAGE FORMS AND STRENGTHS

2.5 mL of a 1% sterile topical ophthalmic solution.

4 CONTRAINDICATIONS

Hypersensitivity to any component of this product.

5 WARNINGS AND PRECAUTIONS

5.1 Topical Ophthalmic Use Only

NOT FOR INJECTION. AzaSite is indicated for topical ophthalmic use only, and should not be administered systemically, injected subconjunctivally, or introduced directly into the anterior chamber of the eye.

5.2 Anaphylaxis and Hypersensitivity with Systemic Use of Azithromycin

In patients receiving systemically administered azithromycin, serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported rarely in patients on azithromycin therapy. Although rare, fatalities have been reported. The potential for anaphylaxis or other hypersensitivity reactions should be considered based on known hypersensitivity to azithromycin when administered systemically.

5.3 Growth of Resistant Organisms with Prolonged Use

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and where appropriate, fluorescein staining.

5.4 Avoidance of Contact Lenses

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

6 ADVERSE REACTIONS

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

The data described below reflect exposure to AzaSite in 698 patients. The population was between 1 and 87 years old with clinical signs and symptoms of bacterial conjunctivitis. The most frequently reported ocular adverse reaction reported in patients receiving AzaSite was eye irritation. This reaction occurred in approximately 1-2% of patients. Other adverse reactions associated with the use of AzaSite were reported in less than 1% of patients and included ocular reactions (blurred vision, burning, stinging and irritation upon instillation, contact dermatitis, corneal erosion, dry eye, eye pain, itching, ocular discharge, punctate keratitis, visual acuity reduction) and non-ocular reactions (dysgeusia, facial swelling, hives, nasal congestion, periocular swelling, rash, sinusitis, urticaria).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B. Reproduction studies have been performed in rats and mice at doses up to 200 mg/kg/day. The highest dose was associated with moderate maternal toxicity. These doses are estimated to be approximately 5,000 times the maximum human ocular daily dose of 2 mg. In the animal studies, no evidence of harm to the fetus due to azithromycin was found. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed.

8.3 Nursing Mothers

It is not known whether azithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when azithromycin is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of AzaSite solution in pediatric patients below 1 year of age have not been established. The efficacy of AzaSite in treating bacterial conjunctivitis in pediatric patients one year or older has been demonstrated in controlled clinical trials [see *Clinical Studies (14)*].

8.5 Geriatric Use

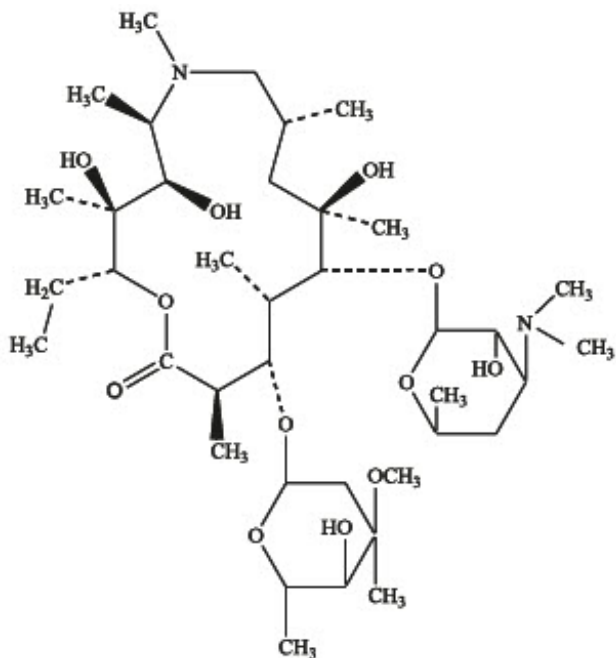
No overall differences in safety or effectiveness have been observed between elderly and younger patients.

11 DESCRIPTION

AzaSite (azithromycin ophthalmic solution) is a 1% sterile aqueous topical ophthalmic solution of azithromycin formulated in DuraSite[®] (polycarbophil, edetate disodium, sodium chloride). AzaSite is an off-white, viscous liquid with an osmolality of approximately 290 mOsm/kg.

Preservative: 0.003% benzalkonium chloride. **Inactives:** mannitol, citric acid, sodium citrate, poloxamer 407, polycarbophil, edetate disodium (EDTA), sodium chloride, water for injection, and sodium hydroxide to adjust pH to 6.3.

Azithromycin is a macrolide antibiotic with a 15-membered ring. Its chemical name is (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-dideoxy-3-C-methyl-3-O-methyl- α -L-ribohexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one, and the structural formula is:



Azithromycin has a molecular weight of 749, and its empirical formula is $C_{38}H_{72}N_2O_{12}$.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Azithromycin is a macrolide antibiotic [see *Clinical Pharmacology (12.4)*].

12.3 Pharmacokinetics

The plasma concentration of azithromycin following ocular administration of AzaSite (azithromycin ophthalmic solution) in humans is unknown. Based on the proposed dose of one drop to each eye (total dose of 100 μ L or 1 mg) and exposure information from systemic administration, the systemic concentration of azithromycin following ocular administration is estimated to be below quantifiable limits (≤ 10 ng/mL) at steady-state in humans, assuming 100% systemic availability.

12.4 Microbiology

Azithromycin acts by binding to the 50S ribosomal subunit of susceptible microorganisms and interfering with microbial protein synthesis.

Azithromycin has been shown to be active against most isolates of the following microorganisms, both *in vitro* and clinically in conjunctival infections [see *Indications and Usage (1)*].

CDC coryneform group G²
Haemophilus influenzae
Staphylococcus aureus
Streptococcus mitis group
Streptococcus pneumoniae

The following *in vitro* data are also available, **but their clinical significance in ophthalmic infections is unknown.** The safety and effectiveness of AzaSite in treating ophthalmological infections due to these microorganisms have not been established.

The following microorganisms are considered susceptible when evaluated using systemic breakpoints. However, a correlation between the *in vitro* systemic breakpoint and ophthalmological efficacy has not been established. This list of microorganisms is provided as an aid only in assessing the potential treatment of conjunctival infections. Azithromycin exhibits *in vitro* minimal inhibitory concentrations (MICs) of equal or less (systemic susceptible breakpoint) against most ($\geq 90\%$) of isolates of the following ocular pathogens:

Chlamydia pneumoniae
Chlamydia trachomatis
Legionella pneumophila
Moraxella catarrhalis
Mycoplasma hominis
Mycoplasma pneumoniae
Neisseria gonorrhoeae
Peptostreptococcus species
Streptococci (Groups C, F, G)
Streptococcus pyogenes
Streptococcus agalactiae
Ureaplasma urealyticum
Viridans group streptococci

2 Efficacy for this organism was studied in fewer than 10 infections.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential. Azithromycin has shown no mutagenic potential in standard laboratory tests: mouse lymphoma assay, human lymphocyte clastogenic assay, and mouse bone marrow clastogenic assay. No evidence of impaired fertility due to azithromycin was found in mice or rats that received oral doses of up to 200 mg/kg/day.

13.2 Animal Toxicology and/or Pharmacology

Phospholipidosis (intracellular phospholipid accumulation) has been observed in some tissues of mice, rats, and dogs given multiple systemic doses of azithromycin. Cytoplasmic microvacuolation, which is likely a manifestation of phospholipidosis, has been observed in the corneas of rabbits given multiple ocular doses of AzaSite. This effect was reversible upon cessation of AzaSite treatment. The significance of this toxicological finding for animals and for humans is unknown.

14 CLINICAL STUDIES

In a randomized, vehicle-controlled, double-blind, multicenter clinical study in which patients were dosed twice daily for the first two days, then once daily on days 3, 4, and 5, AzaSite solution was superior to vehicle on days 6-7 in patients who had a confirmed clinical diagnosis of bacterial conjunctivitis. Clinical resolution was achieved in 63% (82/130) of patients treated with AzaSite versus 50% (74/149) of patients treated with vehicle. The p-value for the comparison was 0.03 and the 95% confidence interval around the 13% (63%-50%) difference was 2% to 25%. The microbiological success rate for the eradication of the baseline pathogens was approximately 88% compared to 66% of patients treated with vehicle (p<0.001, confidence interval around the 22% difference was 13% to 31%). Microbiologic eradication does not always correlate with clinical outcome in anti-infective trials.

16 HOW SUPPLIED/STORAGE AND HANDLING

AzaSite is a sterile aqueous topical ophthalmic formulation of 1% azithromycin.

NDC 82584-307-03: 2.5 mL in 5 mL bottle containing a total of 25 mg of azithromycin in a white, round, low-density polyethylene (LDPE) bottle, with a clear LDPE dropper tip, and a tan colored high density polyethylene (HDPE) eyedropper cap. A white tamper evident over-cap is provided.

NDC 82584-307-04: 2.5 mL in 4 mL bottle containing a total of 25 mg of azithromycin in a white, round, low-density polyethylene (LDPE) bottle, with a clear LDPE dropper tip, and a tan colored high density polyethylene (HDPE) eyedropper cap. A white tamper evident over-cap is provided.

Storage and Handling:

Store unopened bottle under refrigeration at 2° to 8°C (36° to 46°F). Once the bottle is opened, store at 2° to 25°C (36° to 77°F) for up to 14 days. Discard after the 14 days.

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information).

Patients should be advised to avoid contaminating the applicator tip by allowing it to touch the eye, fingers or other sources.

Patients should be directed to discontinue use and contact a physician if any signs of an allergic reaction occur.

Patients should be told that although it is common to feel better early in the course of the therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by AzaSite (azithromycin ophthalmic solution) or other antibacterial drugs in the future.

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

Patients should be advised to thoroughly wash hands prior to using AzaSite.

Patients should be advised to invert the closed bottle (upside down) and shake once

before each use. Remove cap with bottle still in the inverted position. Tilt head back, and with bottle inverted, gently squeeze bottle to instill one drop into the affected eye(s).

Manufactured for: **Thea Pharma Inc.**
Lexington, MA 02420

U.S. Patent No.: 7,758,553

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Sun Pharma

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Rev. 05/22

N10270C2USA/0522A

PATIENT INFORMATION

AzaSite® (A-zuh-site)
(azithromycin ophthalmic solution) 1%

Read this Patient Information before you start using AzaSite® 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 treatment.

What is AzaSite?

AzaSite is a prescription sterile eye drop solution. AzaSite is used to treat bacterial conjunctivitis which is an infection of the eye caused by certain bacteria.

It is not known if AzaSite is safe and effective in children less than 1 year of age.

Information about bacterial conjunctivitis.

Bacterial conjunctivitis is a bacterial infection of the mucous membranes which line the inside of the eyelids. Symptoms may include redness of the eye and discharge. The infection can be spread to other people and to both eyes.

Who should not use AzaSite?

Do not use AzaSite if you are allergic to azithromycin or any of the ingredients in AzaSite. See the end of this Patient Information leaflet for a complete list of the ingredients in AzaSite.

What should I tell my doctor before using AzaSite?

Before you use AzaSite, tell your doctor if you:

- wear contact lenses. Do not wear contact lenses if you have signs or symptoms of bacterial conjunctivitis.
- are pregnant or plan to become pregnant. It is not known if AzaSite will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed. It is not known if AzaSite passes into your breast milk. Talk to your doctor about the best way to feed your baby if you are using AzaSite.

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 doctors and pharmacist when you get a new medicine.

How should I use AzaSite?

- **Read the Instructions for Use at the end of this Patient Information** leaflet for the right way to use AzaSite.
- Use AzaSite exactly as your doctor tells you to use it.
- For the first 2 days place 1 drop of AzaSite in your eye (or eyes) each morning and 1 drop in your eye (or eyes) each evening. Wait 8 to 12 hours after placing your morning drops before you place evening drops in your eye (or eyes).
- For the next 5 days place 1 drop of AzaSite in your eye (or eyes) 1 time each day.
- Make sure you continue to use AzaSite as directed by your doctor even if you feel better after you start using it. Skipping drops can increase the chances that:
 - your medicine will not work well
 - Bacteria can develop resistance, which means in the future your bacterial conjunctivitis may not improve from AzaSite or other drugs that treat infections from bacteria.

What should I be aware of while using AzaSite?

Do not wear contact lenses if you have signs or symptoms of bacterial conjunctivitis and until you have finished your prescribed course of treatment. The symptoms of bacterial conjunctivitis may include:

- discharge coming from the eye
- eye redness
- eye irritation

Only your doctor can tell you if you have bacterial conjunctivitis.

Severe allergic reactions have been reported rarely when azithromycin has been taken by mouth.

- Serious rash or serious allergic reactions may occur. Azithromycin, the active ingredient in AzaSite, may cause a serious rash or a serious allergic reaction. Both of these reactions may need to be treated in a hospital and may be life-threatening.
- Stop taking AzaSite and call your doctor right away or get emergency help if you have any of these symptoms:
 - skin rash, hives, sores in your mouth, or your skin blisters and peels
 - swelling of your face, eyes, lips, tongue, or throat
 - trouble swallowing or breathing

Increased risk of other infections caused by bacteria or fungi.

- Using AzaSite for a long time may cause other bacteria or fungi to grow. If this happens you may get a new infection. Tell your doctor right away if your symptoms do not get better.

What are the possible side effects of AzaSite?

The most common side effect of AzaSite is eye irritation.

Other side effects seen with AzaSite include:

- eye burning, stinging and irritation when the drop hits your eye

- irritation on your eyelid and the skin around your eye
- a feeling of discomfort and irritation or that something is in your eye
- dry eye
- eye pain
- eye itching
- discharge coming from your eye
- changes to the surface of your eye
- blurred vision
- changes in your taste
- hives and rash on your skin
- stuffy nose and sinus infection
- swelling around your eye or of your face

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all of the possible side effects of AzaSite. 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 AzaSite?

- Before you open your AzaSite, store it in the refrigerator between 36°F to 46°F (2°C to 8°C).
- After you open your AzaSite, store it at room temperature or the refrigerator between 36°F to 77°F (2°C to 25°C)
- **AzaSite should not be stored for more than 14 days after opening. After 14 days, throw the AzaSite bottle away.**
- Safely throw away medicine that is out of date or no longer needed.

Keep AzaSite and all medicines out of reach of children.

General information about the safe and effective use of AzaSite

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use AzaSite for a condition for which it was not prescribed. Do not give AzaSite to other people, even if they have the same symptoms that you have. It may harm them.

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

For more information, go to www.azasite.com or call 1-833-838-4028.

What are the ingredients in AzaSite?

Active ingredient: azithromycin

Inactive ingredients: 0.003% benzalkonium chloride, mannitol, citric acid, sodium citrate, poloxamer 407, polycarbophil, edetate disodium (EDTA), sodium chloride, water, and sodium hydroxide.

Instructions for Use

AzaSite® (A-zuh-site)
(azithromycin ophthalmic solution) 1%

Read this Instructions for Use for AzaSite before you start using it 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 treatment.

Important:

- **AzaSite is for use as an eye drop only.**

The checklist below tells you when to use your medicine for each eye that has bacterial conjunctivitis:

<input type="checkbox"/> <input type="checkbox"/>	Day 1: _____	1 drop in the morning and 1 drop in the evening
<input type="checkbox"/> <input type="checkbox"/>	Day 2: _____	1 drop in the morning and 1 drop in the evening
<input type="checkbox"/>	Day 3 _____	1 drop anytime during the day
<input type="checkbox"/>	Day 4 _____	1 drop anytime during the day
<input type="checkbox"/>	Day 5 _____	1 drop anytime during the day
<input type="checkbox"/>	Day 6 _____	1 drop anytime during the day
<input type="checkbox"/>	Day 7 _____	1 drop anytime during the day

This is a total of 9 drops of AzaSite for each infected eye.

- Avoid letting the applicator tip touch your eye, your fingers, or other objects.
- If a drop misses your eye, try again.
- Follow the steps below to use AzaSite correctly.

Before using a new bottle of AzaSite:



Figure A



Figure B

- Hold the bottle straight, turn the tan cap

- Turn the white cap clockwise until it comes off. Throw away the white cap. **See Figure A**

counterclockwise until it comes off. Put the tan cap back on the bottle and close tightly. (This lets out the air.) **See Figure B**

Wash your hands each time you use AzaSite.

To use AzaSite:



Figure C

Step 1. Turn the closed bottle upside down. **See Figure C**



Figure D

Step 2. Shake your hand firmly. This helps move the medicine into the tip of the bottle. **See Figure D**



Figure E

Step 3. Hold the bottle upside down and take off the tan cap. **See Figure E**



Figure F

Step 4. Tilt your head back. Hold the bottle over your eye and gently squeeze the bottle to let 1 drop into each eye that has bacterial conjunctivitis. Put the tan cap back on the bottle and close tightly. **See Figure F**

If a drop does not come out of the bottle, repeat steps one to four.

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

Manufactured for: **Thea Pharma Inc.**
Lexington, MA 02420

U.S. Patent No.: 7,758,553

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Rev. 05/22

N10270C2USA/0522B

PRINCIPAL DISPLAY PANEL - 2.5 mL Bottle Carton

NDC 82584-307-03

AzaSITE[®]

(azithromycin ophthalmic solution) 1%

Sterile 2.5 mL

Rx Only

FOR OPHTHALMIC USE ONLY



AZASITE

azithromycin monohydrate solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:82584-307
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
AZITHROMYCIN MONOHYDRATE (UNII: JTE4MNN1MD) (AZITHROMYCIN ANHYDROUS - UNII:J2KLZ20U1M)		AZITHROMYCIN ANHYDROUS	10 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		0.03 mg in 1 mL		
MANNITOL (UNII: 3OWL53L36A)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
POLYCARBOPHIL (UNII: W25LM17A4W)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
WATER (UNII: 059QF0K00R)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82584-307-02	1 in 1 CARTON	11/01/2022	
1		2.5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:82584-307-03	1 in 1 CARTON	11/01/2022	
2		2.5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA050810	11/01/2022		

Labeler - Thea Pharma Inc. (117787029)

Establishment

Name	Address	ID/FEI	Business Operations
Woodstock Sterile Solutions, Inc.		117895702	manufacture(82584-307) , label(82584-307) , pack(82584-307) , analysis(82584-307)

Revised: 1/2023

Thea Pharma Inc.