DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.
AZASITE® (azithromycin ophthalmic solution) 1% Sterile topical ophthalmic drops

1 INDICATIONS AND USAGE
AZASITE® (azithromycin ophthalmic solution) is a 1% sterile aqueous topical ophthalmic solution of azithromycin formulated in DuraSite® (polydextrose, edetate disodium, sodium chloride). AZASITE® is an off-white, viscous liquid with an osmolality of approximately 290 mOsm/L.

2 DOSAGE AND ADMINISTRATION
Instill 1 drop in the affected eye(s) twice daily, for up to 10 days. For patients one year or older has been demonstrated in controlled clinical trials (see Clinical Studies [14]).

5 WARNINGS AND PRECAUTIONS
5.1 Topical Ophthalmic Use Only
5.2 Anaesthetic and Hypersensitivity with Systemic Use of Azithromycin
5.3 Growth of Resistant Organisms with Systemic Use of Azithromycin
5.4 Avoidance of Contact Lenses
5.5 Prolonged Use
5.6 Systemic Use of Azithromycin
5.7 Hypersensitivity to any component of this product.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

14 CLINICAL STUDIES

12.1 Mechanism of Action
Azithromycin is a macrolide antibiotic that inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit and preventing the translocation of the ribosome from the peptidyl transferase center to the A site on the 16S rRNA of bacteria. This inhibition prevents the incorporation of amino acids into the growing peptide chain, ultimately leading to bacterial cell death.

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

1. Code is numbered item followed by letter

WARNING AND PRECAUTIONS

- For topical ophthalmic use only, (5.1)
- Anaesthetic and hypersensitivity 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)
- 5 WARNINGS AND PRECAUTIONS
- Most common adverse reaction reported in patients was eye irritation (1-2% of patients) (6)
- To report SUSPECTED ADVERSE REACTIONS, contact Akorn, Inc. at 1-800-522-5690 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

7.3 10 5 4 3 2 14
G=67
F=56
E=45
D=34
C=23
A=01
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

9.3 Azithromycin is a macrolide antibiotic to which infections are unknown. Based on the proposed dose of one drop to each eye (total dose of 100 mcL or 1 drop twice daily) 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.

12.3 Pharmacokinetics
The plasma concentration of azithromycin following ocular administration of AZASITE (azithromycin ophthalmic solution) in humans is unknown. Theophylline (a suggested dosed of one drop to each eye (total dose of 100 mcL or 1 drop twice daily) 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 the following microorganisms (in vitro): clinically significant infections [See Indications and Usage (1)].

3 DOSAGE FORMS AND STRENGTHS
2.5 mL of 1% sterile topical ophthalmic solution.

4 CONTRAINDICATIONS
Hyposensitivity (4)

CONTRAINDICATIONS
- Hyposensitivity (4)

FULL PRESCRIBING INFORMATION: CONTENTS*
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
6 ADVERSE REACTIONS
7 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy

FULL PRESCRIBING INFORMATION: CONTENTS*
1 INDICATIONS AND USAGE
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6 ADVERSE REACTIONS
7 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy

If the plasma concentration of azithromycin following ocular administration of AZASITE (azithromycin ophthalmic solution) in humans is unknown. Theophylline (a dose) 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 the following microorganisms (in vitro): clinically significant infections [See Indications and Usage (1)].

3 DOSAGE FORMS AND STRENGTHS
2.5 mL of 1% sterile topical ophthalmic solution.
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%). Microbiological 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 17478-307-03: 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 17478-307-04: 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°C to 8°C (36°F to 46°F). Once the bottle is opened, store at 2°C to 25°C (36°F 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).

Distributed by: Akorn, Inc.
Lake Forest, IL 60045

U.S. Patent Nos.: 6,159,458; 6,239,113; 6,569,443; 6,861,411; 7,056,893; and Patents Pending

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OPZT00N  Rev 11/13