



**An ocular surface condition
causes damage...**



AzaSite[®] Can Restore a Healthy Ocular Surface

By Delivering Significant Anti-Inflammatory and
Antimicrobial Effects Directly to the Site of the Problem^{1,2,3,4}

AzaSite[®] achieved therapeutic concentrations in ocular surface tissues
and maintained them for at least five days after the *last* dose (day 7)⁵

AzaSite[®] (azithromycin ophthalmic solution) 1% is indicated for the treatment of bacterial conjunctivitis caused by the following organisms: CDC coryneform group G*, *Staphylococcus aureus*, *Streptococcus mitis* group, *Streptococcus pneumoniae*, and *Haemophilus influenzae*.

Important Safety Information: AzaSite[®] should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye or otherwise administered systemically. In clinical trials, the most common ocular adverse event was eye irritation, which occurred in 1% to 2% of patients.

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

Please see the brief summary of Prescribing Information on the adjacent page.

For more information, visit www.azasite.com

AzaSITE[®]
(azithromycin ophthalmic solution) 1%

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References: 1. Zhou N, Ma P, Li D-Q, Pflugfelder SC. Azithromycin suppresses pro-inflammatory mediators stimulated by a TLR2 ligand zymosan in human corneal epithelial cells. Poster presented at: 2009 Association for Research in Vision and Ophthalmology Annual Meeting; May 3-7, 2009; Fort Lauderdale, FL. 2. Sadrai Z, Hajrasouliha AR, Chauhan SK, Saban DR, Dastjerdi MH, Dana R. Effect of topical azithromycin on innate immune responses in experimental keratitis. Poster presented at: 2009 Association for Research in Vision and Ophthalmology Annual Meeting; May 3-7, 2009; Fort Lauderdale, FL. 3. Abelson M, Protzko E, Shapiro A, Garces-Soldana A, Bowman L. A randomized trial assessing the clinical efficacy and microbial eradication of 1% azithromycin ophthalmic solution vs tobramycin in adult and pediatric subjects with bacterial conjunctivitis. *Clin Ophthalmol.* 2007;1(2):177-182. 4. Abelson MB, Heller W, Shapiro AM, Si E, Hsu P, Bowman LM. Clinical cure of bacterial conjunctivitis with azithromycin 1%: vehicle-controlled, double-masked clinical trial. *Am J Ophthalmol.* 2008;145:959-965. 5. Stewart WC, Crean CS, Zink RC, Haque R, Hwang DG. Pharmacokinetics of azithromycin and moxifloxacin in human conjunctiva and aqueous humor during and after the approved dosing regimens. Poster presented at: 2009 Association for Research in Vision and Ophthalmology Annual Meeting; May 3-7, 2009; Fort Lauderdale, FL.

AzaSITE[®]

(azithromycin ophthalmic solution) 1%

Sterile topical ophthalmic drops

Initial U.S. Approval: 2007

BRIEF SUMMARY

Before prescribing, please consult the full prescribing information.

INDICATIONS AND USAGE

AzaSite is 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
Streptococcus pneumoniae

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

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.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

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.

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, since patients with a known hypersensitivity to azithromycin or erythromycin were excluded from study.

Growth of Resistant Organisms With Prolonged Use

As with other anti-infectives, prolonged use may result in overgrowth of nonsusceptible 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.

Avoidance of Contact Lenses

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

ADVERSE REACTIONS

The most frequently reported ocular adverse reaction in patients receiving AzaSite was eye irritation. This reaction occurred in approximately 1% to 2% of patients. Other adverse reactions associated with the use of AzaSite were reported in less than 1% of patients and included: burning, stinging and irritation upon instillation, contact dermatitis, corneal erosion, dry eye, dysgeusia, nasal congestion, ocular discharge, punctate keratitis, and sinusitis.

In addition to adverse events reported from clinical trials, the following events have been identified during post approval use of AzaSite. **Eye:** blurring, eyelid swelling, itching, pain, visual acuity reduction. **General:** allergic reactions including facial swelling, hives, periorcular swelling, rash, urticaria.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B. Reproduction studies have been performed in rats and mice at doses up to 200 mg/kg/d. The highest dose was associated with moderate maternal toxicity. These doses are estimated to be approximately 5000 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.

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.

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.

Geriatric Use

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

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.

PATIENT COUNSELING 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 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 are advised to thoroughly wash hands before using AzaSite.

Rx only

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