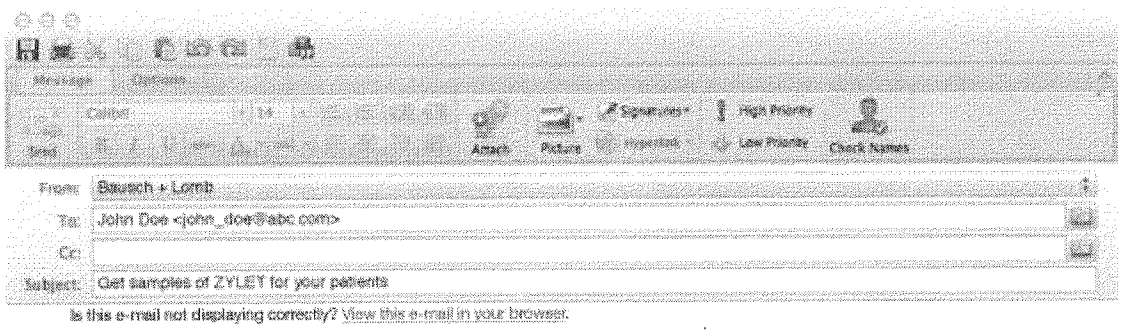

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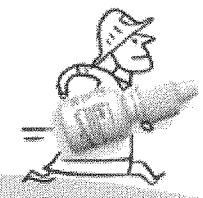
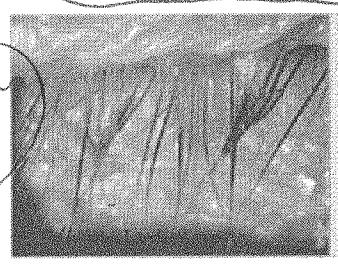


ZYLET®: RELIEF TO THE RESCUE FOR THE TREATMENT OF BLEPHARITIS

Zylet.
loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension

Visit www.mysamplecloset.com/bausch to order FREE ZYLET® samples for your patients.



Treat the signs of blepharitis with ZYLET®

ZYLET® effectively treats these signs of blepharitis[1]:

- Hyperemia
- Scaling or crusting
- Margin hypertrophy

Study design: A parallel-group, double-masked, randomized, prospective study involving 17 independent centers with 276 healthy adult volunteers who were randomized to ZYLET® (n=138) or TobraDex (n=138) administered 4 times daily for 14 days.[1]

Indications

- ZYLET® is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, and where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies
- The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye
- The particular anti-infective drug in this product (tobramycin) is active against the following common bacterial eye pathogens: Staphylococci, including *S. aureus* and *S. epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains. Streptococci, including some of the Group A-beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae*. *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Proteus mirabilis*, *Morganella morganii*, most *Proteus vulgaris* strains, *Haemophilus influenzae*, and *H. aegyptius*, *Moraxella lacunata*, *Acinetobacter calcoaceticus* and some *Neisseria* species

Important Risk Information about ZYLET®

- ZYLET® is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of the ocular structures. ZYLET® is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids
- NOT FOR INJECTION INTO THE EYE
- Prolonged use of ZYLET® is associated with several warnings and precautions, including glaucoma with optic nerve damage, defects in visual acuity, cataract formation, secondary ocular infections, exacerbation or prolongation of viral ocular infections (including herpes simplex), delay in wound healing and increase in bleb formation
- If this product is used for 10 days or longer, intraocular pressure should be monitored. The initial prescription and renewal of the medication order beyond 14 days should be made by a physician only after examination of the patient with the aid of magnification. Fungal infections of the cornea may develop with prolonged use of corticosteroids
- As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Cross-sensitivity to other aminoglycoside antibiotics may occur
- In a 42-day safety study comparing ZYLET® to placebo, the incidence of ocular adverse events reported in greater than 10% of subjects included injection (approximately 20%) and superficial punctate keratitis (approximately 15%). Increased intraocular pressure was reported in 10% (ZYLET®) and 4% (placebo) of subjects. The incidence of clinically significant increases in intraocular pressure ≥10 mm Hg from baseline was reported in 3.6% (4/112) of subjects receiving ZYLET® and 0% (0/56) among subjects receiving placebo. Nine percent (9%) of ZYLET® subjects reported burning and stinging upon instillation

Please see complete information about ZYLET® in the full prescribing information provided here.

Reference: 1. White EM, Macy JI, Bateman KM, Comstock TL. Comparison of the safety and efficacy of loteprednol 0.5%/tobramycin 0.3% with dexamethasone 0.1%/tobramycin 0.3% in the treatment of blepharokeratoconjunctivitis. *Curr Med Res Opin.* 2008;24(1):287-296.

BAUSCH + LOMB

Zylet.
loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension

~~US/ZYL/XX/XXXX~~
US/ZYL/14/0004a

www.BauschSampleVault.com

replace w/ revised PRI attached

1/14

2014