

Therapeutic Class Overview

Ophthalmic Antibiotic Steroid Combinations

INTRODUCTION

- Blepharitis is a chronic inflammatory condition of the eyelids, often presenting with the symptoms of eye irritation and redness. Overgrowth of normal bacterial flora plays a role in the pathophysiology of blepharitis, with the most common causative organisms including *Staphylococcus* species, *Corynebacterium* species, and *Propionibacterium acnes*. The mainstay of the treatment of blepharitis is patient education regarding eyelid hygiene as well as the use of ophthalmic antibiotics. Of note, blepharitis is a chronic condition without definitive cure; therefore, satisfactory results require a long-term commitment to treatment and appropriate expectations. Ophthalmic corticosteroids may also be used acutely to treat exacerbations (*American Academy of Ophthalmology [AAO], 2013[b]*).
- Conjunctivitis occurs worldwide and affects all ages and social strata. This infection rarely causes permanent visual loss or structural damage, and mild cases may be self-limited, as many cases will resolve without treatment in immunocompetent individuals. The most common causative pathogens seen with bacterial conjunctivitis include *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*. Use of ophthalmic antibiotics is associated with earlier clinical and microbiological remission when compared to placebo. The selection of an ophthalmic antibiotic is typically empirical, and the most convenient or least expensive ophthalmic antibiotic is typically effective for most cases of conjunctivitis (*AAO, 2013[c]*; *American Optometric Association [AOA], 2002*).
- Severe bacterial conjunctivitis is characterized by purulent discharge, pain, and marked eye inflammation. In these cases, cultures and slides for gram staining should be obtained, and the results of these laboratory tests should guide the choice of the antibiotic. Methicillin-resistant *S. aureus* has been isolated in patients with bacterial conjunctivitis with increasing frequency and may be resistant to many available ophthalmic antibiotics. In patients with conjunctivitis caused by *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, systemic antibiotic therapy is necessary, and while not necessary, ophthalmic antibiotics are also typically used (*AAO, 2013[c]*; *AOA, 2002*).
- Bacterial keratitis is characterized by an inflammation of the cornea and rarely occurs in the normal eye due to the cornea's natural resistance to infection. However, several predisposing factors such as contact lens wear, trauma, corneal surgery, ocular surface disease, systemic disease, and immunosuppression may alter the defense mechanisms of the ocular surface and allow for infection of the cornea (*Tauber et al, 2011*). Due to corneal scarring or topographic irregularity, many forms of this infection result in visual loss. Untreated or severe bacterial keratitis can result in corneal perforation and may develop into endophthalmitis and result in the loss of the eye. The most common causative organisms of bacterial keratitis include *Staphylococci* and gram-negative rods, of which the most frequent organisms identified are *Pseudomonas* species. Ophthalmic antibiotics are the preferred method of treatment in many cases, and antibiotic ointments may be useful at bedtime in less severe cases or as adjunctive therapy. In addition, broad-spectrum ophthalmic antibiotics are used initially as empiric treatment. In severe cases, patients should be followed daily until stabilization or clinical improvement is documented (*AAO, 2013[a]*).
- Though not Food and Drug Administration-approved, ophthalmic antibiotics are routinely used to prevent postoperative infections after eye surgeries such as refractive surgeries and cataract removal, while ophthalmic corticosteroids may also be used to reduce inflammation associated with surgeries (*AAO, 2016*; *AAO, 2017*; *AOA, 2004*).
- Ophthalmic antibiotic and steroid combinations are included in this review. Poly-Pred (neomycin/polymyxin/prednisolone) was discontinued by Allergan in 2011, and a generic product is not available (*Drugs@FDA, 2018*; *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, 2018*). However, other polymyxin/neomycin products are available with another corticosteroid.
- Medispan class: Ophthalmic Steroid Combinations

Table 1. Medications Included Within Class Review

| Drug | Generic Availability |
|--|----------------------|
| bacitracin/neomycin/polymyxin/hydrocortisone | ✓ |
| Blephamide* (sulfacetamide/prednisolone) | ✓ (solution only) |

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| Drug | Generic Availability |
|--|----------------------|
| Maxitrol (neomycin/polymyxin/dexamethasone) | ✓ |
| neomycin/polymyxin/hydrocortisone | ✓ |
| Pred-G (gentamicin/prednisolone) | - |
| Tobradex, Tobradex ST (tobramycin/dexamethasone) | ✓ (suspension only) |
| Zylet (tobramycin/loteprednol) | - |

*Blephamide is available as suspension and ointment; solution is only available as a generic.

(*Drugs @FDA 2018, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations 2018*)

INDICATIONS

Table 2. Food and Drug Administration Approved Indications

- Ocular corticosteroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of corticosteroid use in certain infective conjunctivitis 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.

| Indication | bacitracin/neomycin/ polymyxin/ hydrocortisone | Blephamide (sulfacetamide/ prednisolone) | Maxitrol (neomycin/polymyxin/d examethasone) | neomycin/polymyxin/h ydrocortisone | Pred-G (gentamicin/ prednisolone) | Tobradex, Tobradex ST (tobramycin/ dexamethasone) | Zylet (tobramycin/ loteprednol) |
|---|--|--|--|---------------------------------------|---|---|---------------------------------------|
| Steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists. | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

(Prescribing information: bacitracin/neomycin/polymyxin/hydrocortisone, 2011; BLEPHAMIDE ointment, 2014; BLEPHAMIDE, suspension 2017; MAXITROL suspension, 2018; MAXITROL ointment, 2017; neomycin/polymyxin/hydrocortisone, 2011; PRED-G ointment, 2017; PRED-G suspension, 2017; sulfacetamide/prednisolone solution, 2013; TOBRADEX ointment, 2018; TOBRADEX suspension, 2015; TOBRADEX ST, 2011; ZYLET, 2016)

- Information on indications, mechanism of action, pharmacokinetics, dosing, and safety has been obtained from the prescribing information for the individual products, except where noted otherwise.

CLINICAL EFFICACY SUMMARY

- Clinical trials have demonstrated that ophthalmic antibiotic steroid combination products are effective in treating patients with external ocular infections, including bacterial blepharitis, conjunctivitis, and blepharokeratoconjunctivitis (*Rhee et al 2007; Shulman et al 1996; White et al 2008*).
- In one study involving patients with moderate blepharokeratoconjunctivitis, reductions in blepharitis and conjunctivitis symptom scores were greater with ophthalmic tobramycin/dexamethasone therapy compared to ophthalmic tobramycin/loteprednol therapy, while the reductions in keratitis symptom scores were similar between the 2 treatment groups (*Rhee et al 2007*).
- In another study, the reduction in composite symptom scores in patients with blepharokeratoconjunctivitis was similar between the tobramycin/dexamethasone and tobramycin/loteprednol groups; however, the increase in intraocular pressure was significantly greater with tobramycin/dexamethasone than tobramycin/loteprednol (*White et al 2008*). Another pooled analysis of data from 2 trials in patients with blepharokeratoconjunctivitis who were randomized to either

tobramycin/dexamethasone or tobramycin/loteprednol found similar effects on blepharitis severity; however, tobramycin/loteprednol demonstrated a better safety profile with respect to intraocular pressure (Comstock 2017).

- Another study involving patients with moderate to severe acute blepharitis/blepharoconjunctivitis showed initial therapy with the combination of tobramycin/dexamethasone ST provides faster inflammation relief than azithromycin ophthalmic based on a statistically significant lower mean global score ($p = 0.0002$) (Torkildsen et al 2011).
- One study showed that when compared to dexamethasone alone, neomycin/polymyxin B/dexamethasone resulted in significantly greater bacterial eradication and decrease in bacterial count in patients with bacterial blepharitis or conjunctivitis; however, the reduction in signs and symptoms of ocular infection was similar between the 2 treatment groups (Shulman et al 1996).
- In patients undergoing cataract and posterior chamber lens implant surgery, treatment with ophthalmic gentamicin resulted in lower bacterial colony count compared to ophthalmic neomycin/polymyxin B/dexamethasone at days 6 and 8 ($p = 0.033$); however, there was no significant difference between the 2 groups with regard to the degree of intraocular inflammation or the global assessment of the success of therapy and local tolerance (p value not reported) (Van Endt et al 1997). In a separate study involving patients undergoing cataract extraction by either manual extraction or phacoemulsification with intraocular lens implantation, ophthalmic tobramycin/dexamethasone was non-inferior to ophthalmic neomycin/polymyxin B/dexamethasone concerning inflammation scores at days 3, 8, 14, and 21. Inflammation scores in the ophthalmic tobramycin/dexamethasone group were significantly lower than scores seen in the ophthalmic neomycin/polymyxin B/gramicidin group at days 8, 14, and 21 ($p < 0.05$ for all), and scores in the ophthalmic neomycin/polymyxin B/dexamethasone group were significantly lower than those seen in the ophthalmic neomycin/polymyxin B/gramicidin group at day 8 ($p < 0.05$) (Notivol et al 2004).

CLINICAL GUIDELINES

- Guidelines published by the AAO recommend that blepharitis be treated with ophthalmic bacitracin or ophthalmic erythromycin and note that macrolide antibiotics may have anti-inflammatory activity with regard to the treatment of blepharitis. To prevent resistance, topical antibiotics with different mechanisms of action can be used intermittently if needed (AAO, 2013[b]).
- Guidelines state that keratitis should be treated with a broad-spectrum ophthalmic antibiotic that may be selected based on the isolated organism, and if no organism is identified, treatment with cefazolin plus either gentamicin or tobramycin or an ophthalmic fluoroquinolone alone is recommended. The AAO guideline also notes that fewer gram-positive cocci are resistant to ophthalmic gatifloxacin and moxifloxacin hydrochloride than other fluoroquinolones (AAO 2013[a]).
- For the treatment of bacterial conjunctivitis, it is recommended that the least expensive or most convenient broad-spectrum antibiotic be selected for a 5- to 7-day course of treatment (AAO 2013[b]; AOA 2002).
- Short-term use of ophthalmic corticosteroids is recommended by treatment guidelines to reduce inflammation in the treatment of blepharitis, conjunctivitis, and keratitis, and can be considered in postoperative prophylaxis (AAO 2016; AAO 2013[a]; AAO 2013[b]; AAO 2013[c]).

SAFETY SUMMARY

- Prolonged use of corticosteroids may result in the following: development of glaucoma, corneal or scleral thinning which can lead to perforation, suppression of host response causing secondary infection, and/or purulent infections of the eye may be masked or activity enhanced.
- If using these products for longer than 10 days, monitor intraocular pressure (IOP). Use after cataract surgery may delay healing. Overgrowth of nonsusceptible organisms, including fungi, may occur.
- Blephamide (sulfacetamide/prednisolone) may cause acute anterior uveitis in susceptible individuals, primarily Blacks. The *p*-aminobenzoic acid present in purulent exudates competes with sulfonamides and can reduce their effectiveness.
- Reactions occurring most often from the presence of the anti-infective ingredient are allergic sensitization reactions including itching, swelling, and conjunctival erythema. The reactions due to the corticosteroid component are elevation of IOP with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing.

DOSING AND ADMINISTRATION

Table 3. Dosing and Administration

Data as of May 8, 2018 MG-U/RR-U

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| Drug | Available Formulations | Usual Recommended Frequency | Comments |
|--|--|---|--|
| bacitracin/ neomycin/ polymyxin/ hydrocortisone | ophthalmic ointment: bacitracin zinc 400 units/neomycin sulfate 3.5 mg/polymyxin B sulfate 10,000 units/ hydrocortisone 10 mg/gram | Apply to the affected eye(s) every 3 or 4 hours, depending on the severity of the condition. | Not more than 8 grams should be prescribed initially. |
| Blephamide (sulfacetamide/ prednisolone) | ophthalmic ointment: sulfacetamide 10%/ prednisolone 0.2% ophthalmic solution: sulfacetamide 10%/ prednisolone sodium 0.23% ophthalmic suspension: sulfacetamide 10%/ prednisolone 0.2% | Ointment Apply ½ inch ribbon to the conjunctival sac(s) 3 or 4 times daily and once or twice at night. Solution Instill 2 drops into the eye(s) every 4 hours. Suspension Instill 2 drops into the conjunctival sac(s) every 4 hours during the day and at bedtime. | Ointment: Not more than 8 grams should be prescribed initially. Solution and suspension: Not more than 20 mL should be prescribed initially. Suspension: shake well before using. |
| Maxitrol (neomycin/ polymyxin/ dexamethasone) | ophthalmic ointment: neomycin 3.5 mg/ polymyxin B sulfate 10,000 units/ dexamethasone 0.1% per gram ophthalmic suspension: neomycin 3.5 mg/ polymyxin B sulfate 10,000 units/ dexamethasone 0.1% per mL | Ointment Apply a small amount into the conjunctival sac(s) up to 3 or 4 times daily. Suspension <i>Mild disease:</i> One to 2 drops in the conjunctival sac(s) up to 4 to 6 times daily. <i>Severe disease:</i> Drops may be used hourly, being tapered to discontinuation as the inflammation subsides. | Ointment: Not more than 8 grams should be prescribed initially. Suspension: Not more than 20 mL should be prescribed initially. |
| neomycin/ polymyxin/ hydrocortisone | ophthalmic suspension: neomycin sulfate 3.5 mg/polymyxin B sulfate 10,000 units/hydrocortisone 10 mg/mL | Instill 1 or 2 drops into the affected eye(s) every 3 to 4 hours depending on the severity of the infection. | Not more than 20 mL should be prescribed initially. |
| Pred-G (gentamicin/ prednisolone) | ophthalmic ointment: gentamicin 0.3%/ prednisolone acetate 0.6% ophthalmic suspension: gentamicin 0.3%/ prednisolone acetate 1% | Ointment Apply ½ inch ribbon in the conjunctival sac(s) 1 to 3 times daily. Suspension Instill 1 drop into the conjunctival sac(s) 2 to 4 times daily. During the initial 24 to 48 hours, the dosing | Ointment: Not more than 8 grams should be prescribed initially. Suspension: Not more than 20 mL should be prescribed initially. |

| Drug | Available Formulations | Usual Recommended Frequency | Comments |
|--|--|--|---|
| | | may be increased up to 1 drop every hour. | |
| Tobradex, Tobradex ST (tobramycin/dexamethasone) | <p>ophthalmic ointment: tobramycin 0.3%/dexamethasone 0.1%</p> <p>ophthalmic suspension: tobramycin 0.3%/dexamethasone 0.1%</p> <p>ophthalmic ST suspension: tobramycin 0.3%/dexamethasone 0.05%</p> | <p>Ointment Apply ½ inch ribbon into the conjunctival sac(s) up to 3 or 4 times daily.</p> <p>Suspension Instill 1 or 2 drops into the conjunctival sac(s) every 4 to 6 hours. During the initial 24 to 48 hours, the dosage may be increased to 1 or 2 drops every 2 hours.</p> <p>ST Suspension Instill 1 drop into the conjunctival sac(s) every 4 to 6 hours. During the initial 24 to 48 hours, the dosage may be increased to 1 drop every 2 hours.</p> | <p>Ointment: Not more than 8 grams should be prescribed initially.</p> <p>Suspension, ST Suspension: Not more than 20 mL should be prescribed initially. Shake well before using.</p> |
| Zylet (tobramycin/loteprednol) | ophthalmic suspension: tobramycin 0.3%/loteprednol etabonate 0.5% | Instill 1 or 2 drops into the conjunctival sac(s) every 4 to 6 hours. During the initial 24 to 48 hours, the dosing may be increased, to every 1 to 2 hours. | Not more than 20 mL should be prescribed initially. Shake vigorously before using. |

See the current prescribing information for full details

CONCLUSION

- Ophthalmic antibiotic steroid combination products are indicated for the treatment of steroid-responsive ocular inflammatory conditions where the presence or risk of a superficial bacterial ocular infection exists. At least 1 generic is available in each formulation: ointment, solution, and suspension.
- In comparative clinical trials, no one ophthalmic antibiotic steroid combination product has been shown to be more effective than another with regard to symptom improvement or reduction of postoperative inflammation.
- In clinical studies, adverse events were mild with no significant difference seen with regard to the rate of adverse events. Common adverse events reported include burning, ocular discomfort, stinging, and tearing.
- Ophthalmic antibiotic steroid combinations are not intended to be used for prolonged periods of time in order to avoid overgrowth of non-susceptible organisms and reduce the risk of resistance. Should a super-infection occur, the ophthalmic antibiotic should be discontinued, and an alternative therapy should be initiated. Steroid-containing ophthalmic products may also increase the risk of intraocular pressure elevation, cataract formation, and delayed healing after cataract surgeries, and should be used with caution.
- Guidelines published by the AAO recommend that blepharitis be treated with ophthalmic bacitracin or ophthalmic erythromycin and note that macrolide antibiotics may have anti-inflammatory activity with regard to the treatment of blepharitis. To prevent resistance, topical antibiotics with different mechanisms of action can be used intermittently if needed (AAO 2013[b]).
- Guidelines state that keratitis should be treated with a broad-spectrum ophthalmic antibiotic that may be selected based on the isolated organism, and if no organism is identified, treatment with cefazolin plus either gentamicin or tobramycin or an ophthalmic fluoroquinolone alone is recommended. The AAO guideline also notes that fewer gram-positive cocci are resistant to ophthalmic gatifloxacin and moxifloxacin hydrochloride than other fluoroquinolones (AAO 2013[a]).

- For the treatment of bacterial conjunctivitis, it is recommended that the least expensive or most convenient broad-spectrum antibiotic be selected for a 5- to 7-day course of treatment (AAO 2013[c], AOA 2002).
- Short-term use of ophthalmic corticosteroids is recommended by treatment guidelines to reduce inflammation in the treatment of blepharitis, conjunctivitis, and keratitis and can be considered in postoperative prophylaxis (AAO 2016; AAO 2013[a]; AAO 2013[b]; AAO 2013[c]).

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