

**CONSUMER INFORMATION**Pr **BLEPHAMIDE**<sup>®</sup>

**Sulfacetamide sodium 10.0% w/v and  
prednisolone acetate 0.2% w/v  
Sterile ophthalmic suspension  
Anti-inflammatory / Antibacterial**

**ABOUT THIS MEDICATION****What the medication is used for:**

**BLEPHAMIDE**<sup>®</sup> is indicated for the treatment of nonpurulent blepharitis and blepharoconjunctivitis (seborrheal, staphylococcal, allergic); nonpurulent conjunctivitis (allergic and bacterial).

**What it does:**

**BLEPHAMIDE**<sup>®</sup> is an anti-bacterial (effective against a broad range of pathogens, including staphylococci). The prednisolone component effectively counters allergic and inflammatory manifestations.

**When it should not be used:**

Do not use **BLEPHAMIDE**<sup>®</sup> if you have:

- viral diseases of the cornea and conjunctiva, including superficial (or epithelial), acute herpes simplex, varicella, and vaccinia
- mycobacterial infection of the eye
- acute purulent untreated infections of the eye, which like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid
- tuberculosis of the eye; fungal disease of the eye; patients with a history of hypersensitivity to any of the components of the product

**What the medicinal ingredient is:**

Sulfacetamide sodium and prednisolone acetate

**What the important nonmedicinal ingredients are:**

benzalkonium chloride 0.0044% (as preservative), edetate disodium, polysorbate 80, polyvinyl alcohol (Liquifilm<sup>®</sup>), potassium phosphate monobasic, sodium phosphate dibasic and sodium thiosulfate.

**What dosage forms it comes in:**

Ophthalmic suspension, sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.2% w/v

**WARNINGS AND PRECAUTIONS**

As with all corticosteroids, **BLEPHAMIDE**<sup>®</sup> may mask, activate or enhance infection. If the infection does not respond promptly, **BLEPHAMIDE**<sup>®</sup> should be discontinued until the infection has been controlled by other means.

**Severe Reactions**

Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia and other blood dyscrasias.

**Sensitivity reactions**

Sensitizations may recur when a sulfonamide is readministered, irrespective of the route of administration. Sensitivity reactions have been reported in individuals with no prior history of sulfonamide hypersensitivity. Use with caution in patients with known or suspected sensitivity to sulfonamides. If sensitivity or other adverse reactions such as skin rash, increase in purulent discharge, or aggravation of inflammation or pain occur, the patient should discontinue medication and consult a physician.

Cross-sensitivity between different sulfonamides or between corticosteroids may occur.

**Corneal and Scleral Thinning**

Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.

**Delayed Healing and Bleb Formation**

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

**Masking Acute Purulent Infections**

Acute purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication.

**Potential Effects of Prolonged Use**

Prolonged use of topical anti-bacterial agents may give rise to overgrowth of nonsusceptible organisms including fungi. Bacterial resistance to sulfonamides may also develop. A significant percentage of staphylococcal isolates are resistant to sulfonamides.

As extended use may cause increased intraocular pressure (IOP) in susceptible individuals, resulting in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision. Corticosteroids should be used with caution in the presence of narrow angle glaucoma; IOP should be checked frequently.

Reports in the literature indicate that posterior subcapsular lenticular opacities have been reported to occur after heavy or protracted use of topical ophthalmic corticosteroids.

The possibility of adrenal suppression should be considered with prolonged, frequent use of high dose topical steroids, particularly in infants and children.

Eye drops containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for IOP.

Silver preparations, such as silver nitrate, mild silver protein (topical sulfonamides are incompatible with silver salts; concurrent use is not recommended).

Ophthalmologic examinations are recommended during long-term therapy. Check with physician if there is no improvement after 5 to 7 days of therapy or if condition worsens.

### Secondary Ocular Infections

Prolonged use may suppress the host immune response in ocular tissues and thus increase the possibility of secondary ocular infections.

When signs of chronic ocular inflammation persist following prolonged corticosteroid dosing, the possibility of fungal infections of the cornea should be considered. Fungal cultures should be taken when appropriate.

Use of intraocular steroids may also prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.

### Examination of the Patient

Eyelid cultures and tests to determine the susceptibility of organisms to sulfacetamide may be indicated if signs and symptoms fail to improve after 2 days.

### Effects on Ability to Drive and Use Machines

Upon instillation, patients may experience transient blurred vision which may impair the ability to drive or use machinery. If affected, patients should not drive or use machinery until their vision has cleared.

**BEFORE** you use **BLEPHAMIDE**<sup>®</sup>, talk to your doctor or pharmacist:

- if you have used corticosteroids before
- if you are pregnant as safety of the use of topical steroids during pregnancy have not been established and it is not known whether **BLEPHAMIDE**<sup>®</sup> can cause fetal harm when administered to a pregnant woman. **BLEPHAMIDE**<sup>®</sup> should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Administration of corticosteroids to pregnant

animals has been associated with abnormalities of fetal development.

- if you are breastfeeding as it is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids appear in breast milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Systemically administered sulfonamides are capable of producing kernicterus in infants of lactating women. Because of the potential for serious adverse reactions in nursing infants from **BLEPHAMIDE**<sup>®</sup>, a decision should be made whether to discontinue nursing or to discontinue the medication.

Safety and effectiveness in pediatric patients below the age of 6 years have not been established.

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

## INTERACTIONS WITH THIS MEDICATION

The effectiveness of sulfonamides may be reduced by the *para*-aminobenzoic acid present in purulent exudates and certain local anesthetics that are esters of *p*-aminobenzoic acid.

**BLEPHAMIDE**<sup>®</sup> is incompatible with silver preparations.

## PROPER USE OF THIS MEDICATION

Shake well before using. Instill one drop in affected eye 2 to 4 times daily, depending upon the severity of the condition.

If signs and symptoms fail to improve after two days, the patient should be re-evaluated.

The dosing of **BLEPHAMIDE**<sup>®</sup> may be reduced, but care should be taken not to discontinue therapy prematurely. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of applications.

In general, during early or acute stages of blepharitis, **BLEPHAMIDE**<sup>®</sup> produces results most rapidly and most efficiently— with instillation directly into the eye, with the excess spread on the lid (Method I). When the condition is confined to the lid, however, **BLEPHAMIDE**<sup>®</sup> may be applied directly to the site of the lesion (Method II).

### METHOD I: IN THE EYE AND ON THE LID

1. Wash hands carefully. Tilt head back and drop 1 drop into the eye.

2. Close the eye, and spread the excess medication, present after closing the eye, over the full length of the upper and lower lids.
3. Do not wipe any of the medication off the lids. It will dry completely in 4 or 5 minutes to a clear film that remains on the lid for several hours – it cannot be seen by others, nor will it interfere with vision.
4. The medication should be washed off the lids once or twice daily. However, it should be reapplied after each washing.

#### METHOD II: ON THE LID

1. Wash hands carefully. With head tilted back and eye closed, drop 1 drop onto the lid preferably at the corner of the eye close to the nose.
2. Spread the medication over the full length of the upper and lower lids.
3. Do not wipe away any medication – it will dry in 4 or 5 minutes to a clear, invisible film which will remain on the lid for several hours.
4. The medication should be washed off the lids once or twice daily. However, it should be reapplied after each washing.

Contact lenses should not be worn during the use of this product.

To prevent eye injury or contamination, care should be taken to avoid touching the bottle tip to the eye or to any other surface. The use of the bottle by more than one person may spread infection. Keep bottle or tube tightly closed when not in use.

#### **Overdose:**

Overdose by the topical ophthalmic route will not ordinarily cause acute problems.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Extended ophthalmic use of corticosteroid drugs may cause increased IOP in certain individuals and in those diseases causing thinning of the cornea, perforation has been known to occur.

Frequent or intensive use of ophthalmic adrenocorticoids may retard corneal healing.

Itching, redness, swelling or other signs of irritation not present before therapy or blurred vision, eye pain, headache, seeing halos around lights, cataract, glaucoma, or ocular hypertension, optic nerve damage, drooping of the eyelids, or unusually large pupils occur more or less frequently and may require medical attention.

Reactions occurring most often from the presence of the anti-infective component are allergic sensitization. Stinging, burning or watering of the eyes occur less frequently and need medical attention if they continue or are bothersome.

Systemic adverse reactions may occur with prolonged use of steroids.

The following adverse reactions have been identified during post-approval use of **BLEPHAMIDE®**. Because reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Adverse reactions have occurred with corticosteroid/anti-infective combination drugs which can be attributed to the corticosteroid component, the anti-infective component, or the combination. Reactions occurring with **BLEPHAMIDE®** include: eye irritation, eye pruritus, hypersensitivity, and ocular hyperemia.

Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias (See **WARNINGS AND PRECAUTIONS**).

The reactions due to the corticosteroid component in decreasing order of frequency are: elevation of IOP with possible development of glaucoma and infrequent optic nerve damage; and posterior subcapsular cataract formation. In addition, these preparations have also been reported to cause: dysgeusia, foreign body sensation, headache, mydriasis, pruritus (skin), rash, urticaria, and visual disturbance (blurry vision).

#### **HOW TO STORE IT**

**BLEPHAMIDE®** should be stored at 15° to 25°C. Protect from freezing and light. Store in an upright position.

Sulfonamide solutions, on long standing and exposure to heat and light, will darken in color and should be discarded if they become dark brown. Yellowing does not affect activity.

Keep out of reach or sight of children.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Allergan Inc., at: 1-800-668-6424

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