

**CONSUMER INFORMATION**

Pr **BLEPHAMIDE® S.O.P.®**

**Sulfacetamide sodium 10.0% w/v and**

**prednisolone acetate 0.2% w/v**

**Sterile ophthalmic ointment**

**Steroid / Antibacterial**

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

**BLEPHAMIDE®** ointment is indicated for the treatment of corticosteroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where bacterial infection or a risk of bacterial infection exists.

**BLEPHAMIDE®** ointment is also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns.

**What it does:**

**BLEPHAMIDE®** is a potent antibacterial (effective against a broad range of pathogens, including staphylococcus aureus). The prednisolone content effectively counters the allergic and inflammatory manifestations of blepharitis.

**When it should not be used:**

Do not use **BLEPHAMIDE®** if you have:

- superficial (or epithelial) herpes simplex keratitis (dendritic keratitis), purulent untreated infections, vaccinia, varicella and most other viral diseases of the cornea and conjunctiva
- mycobacterial infection of the eye
- ocular tuberculosis, fungal diseases of the eye
- individuals with known or suspected hypersensitivity to sulfonamides or to any components of the medication, other corticosteroids

**What the medicinal ingredient is:**

Sulfacetamide sodium and prednisolone acetate

**What the important nonmedicinal ingredients are:**

Lanolin alcohol, mineral oil, petrolatum and white petrolatum

**What dosage forms it comes in:**

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

**WARNINGS AND PRECAUTIONS**

In diseases due to microorganisms, infection may be masked, enhanced or activated by the steroid.

**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 untoward 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.

As with all sulfonamide preparations, severe sensitivity reactions, e.g. Stevens-Johnson syndrome, fever, skin rash, GI disturbances and bone marrow depression have been identified in individuals with no prior history of sulfonamide hypersensitivity.

**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.

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.

**Corneal and Scleral Thinning**

Various ocular diseases and long-term use of topical corticosteroids have been known to cause 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 ophthalmic steroid ointments after cataract surgery may retard corneal 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.

**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 ocular steroids may 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 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 are

secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman. 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 are inactivated by the *para*-aminobenzoic acid present in purulent exudates and certain local anesthetics that are esters of *p*-aminobenzoic acid.

**Topical sulfonamides are incompatible with silver salts, concurrent use is not recommended.**

**PROPER USE OF THIS MEDICATION**

A small amount of **BLEPHAMIDE**<sup>®</sup> should be applied to the conjunctival sac three or four times daily and once or twice at night.

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.

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

Corticosteroid-containing preparations have been reported to cause acute anterior uveitis. Ocular irritation, blurred vision, headache, keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis have been reported occasionally following local use of corticosteroids.

Reactions occurring most often from the presence of the anti-infective component are allergic sensitization.

Systemic adverse reactions may occur with prolonged use of steroids.

The following adverse reactions have been identified during post-approval use of **BLEPHAMIDE**<sup>®</sup>. 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**<sup>®</sup> 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**<sup>®</sup> 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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