

PRESCRIBING INFORMATION
INCLUDING PATIENT MEDICATION INFORMATION

Pr **BLEPHAMIDE®**

Sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.2% w/v

Sterile ophthalmic suspension

Anti-inflammatory / Antibacterial

Allergan Inc.
Markham, ON
L6G 0B5

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PRESCRIBING INFORMATION

NAME OF DRUG

Pr **BLEPHAMIDE**[®]

Sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.2% w/v

THERAPEUTIC CLASSIFICATION

Anti-inflammatory / Antibacterial

MECHANISM OF ACTION

BLEPHAMIDE[®] (sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.2% w/v) is an anti-bacterial (effective against a broad range of pathogens, including staphylococci). The prednisolone component effectively counters allergic and inflammatory manifestations.

INDICATIONS

BLEPHAMIDE[®] is indicated for the treatment of nonpurulent blepharitis and blepharoconjunctivitis (seborrheal, staphylococcal, allergic); nonpurulent conjunctivitis (allergic and bacterial).

BLEPHAMIDE[®] contains an antibacterial ingredient, sulfacetamide sodium. To reduce the development of drug-resistant bacteria and maintain the effectiveness of sulfacetamide sodium, **BLEPHAMIDE**[®] should only be used for the authorized indication.

CONTRAINDICATIONS

Do not use **BLEPHAMIDE**[®] 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

WARNINGS AND PRECAUTIONS

As with all corticosteroids, **BLEPHAMIDE**[®] may mask, activate or enhance infection. If the infection does not respond promptly, **BLEPHAMIDE**[®] 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

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.

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.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, consider evaluating for possible causes which may include cataract, glaucoma or rare diseases such as central serous

chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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.

Pregnant women

The safety of the use of topical steroids during pregnancy have not been established and it is not known whether **BLEPHAMIDE**[®] can cause fetal harm when administered to a pregnant woman. **BLEPHAMIDE**[®] 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.

Breast-feeding

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**[®], a decision should be made whether to discontinue nursing or to discontinue the medication.

Pediatrics

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 in younger patients.

Geriatrics

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

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing **BLEPHAMIDE**[®] in the absence of authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth

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

DRUG INTERACTIONS

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[®] is incompatible with silver preparations; concurrent use is not recommended.

Although the systemic exposure is expected to be low with ophthalmic corticosteroid administration, co-treatment with CYP3A inhibitors such as HIV drugs, clarithromycin, erythromycin, ketoconazole, itraconazole, voriconazole, fluconazole, aprepitant, diltiazem and verapamil, may increase the risk of systemic corticosteroid-related side-effects.

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

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.

Administration

The dosing of **BLEPHAMIDE**[®] 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**[®] 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**[®] 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 tightly closed when not in use.

OVERDOSAGE

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.

ADVERSE REACTIONS

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).

POST-MARKET ADVERSE DRUG REACTIONS

The following adverse reactions have been identified during post approval use of **BLEPHAMIDE®**. Because these 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.

Eye disorders: eye discharge, eye swelling, eyelid edema, eyelid erythema, lacrimation increased

Immune system disorders: hypersensitivity including signs and symptoms related to allergic skin reactions (e.g. skin pruritus, rash, urticaria)

Nervous system disorders: dizziness

STORAGE AND STABILITY

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.

DOSAGE FORM

BLEPHAMIDE[®] is supplied sterile in opaque white low-density polyethylene (LDPE) plastic bottles with droppers with white high impact high impact polystyrene (HIPS) caps.

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

PrBLEPHAMIDE®

Sulfacetamide sodium and prednisolone acetate

Sterile ophthalmic suspension

Read this carefully before you start taking BLEPHAMIDE® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about BLEPHAMIDE®.

What is BLEPHAMIDE® used for?

BLEPHAMIDE® is used to treat inflammatory conditions of the eye and eyelid.

BLEPHAMIDE® contains an antibacterial called sulfacetamide sodium, and it should be used exactly as directed by your healthcare professional.

How does BLEPHAMIDE® work?

BLEPHAMIDE® reduces inflammation and stops bacteria from growing in your eye and eyelid.

What are the ingredients in BLEPHAMIDE®:

Medicinal ingredients: Sulfacetamide sodium and prednisolone acetate

Non-medicinal ingredients: Benzalkonium chloride 0.0044% (as preservative), edetate disodium, polysorbate 80, polyvinyl alcohol (Liquifilm®), potassium phosphate monobasic, sodium phosphate dibasic and sodium thiosulfate.

BLEPHAMIDE® comes in the following dosage forms:

As an ophthalmic suspension containing sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.2% w/v

Do not use BLEPHAMIDE® if you:

- have a viral infection of the eye called herpes keratitis
- have other viral infections of the eye
- have other mycobacterial infection of the eye
- have eye infections with pus
- have tuberculosis infection of the eye
- have fungal infection of the eye
- are allergic to sulfacetamide sodium, prednisolone acetate or any other ingredient in **BLEPHAMIDE®**
- are allergic to antibiotics called sulfonamides
- are allergic to medicines called corticosteroids

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use BLEPHAMIDE®. Talk about any health conditions or problems you may have, including if you :

- are pregnant or planning to become pregnant
- are breastfeeding or planning to breast-feed
- have an eye condition called glaucoma
- recently had cataract surgery
- have corneal or scleral tissue damage which is damage to the outside part of your eyeball

Other warnings you should know about:

It is not known if **BLEPHAMIDE®** is safe and effective in children younger than 6 years of age.

Driving and Using Machines

Your vision may be temporarily blurry after using **BLEPHAMIDE®**. Wait until your vision is clear before driving or using

machines.

Potential Effects of Prolonged Use

Long term use may result in a new infection of your eye which does not respond to **BLEPHAMIDE®**.

Eye drops containing prednisolone acetate, like **BLEPHAMIDE®**, should not be used for more than 10 days unless your healthcare professional has told you to. If so, your healthcare professional will closely monitor your condition and regularly check your eye pressure while you are using **BLEPHAMIDE®**.

New Eye Infections

Using corticosteroids, like **BLEPHAMIDE®**, especially for a long time, can affect how your body handles infections. Infections caused by bacteria, viruses or fungi can be hidden or can get worse when you use **BLEPHAMIDE®**. Your body's ability to fight infection may also be reduced. This can make you more likely to get new eye infections. If you notice any symptoms of an infection, such as eye swelling or redness that is not getting better, eye discharge, fever and chills, or you have extreme fatigue, talk to your healthcare professional immediately.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BLEPHAMIDE®:

- local anesthetics
- silver salts which are medicines used to treat eye infections
- medicines used to treat HIV infection
- antibiotics used to treat bacterial infections such as; clarithromycin, erythromycin
- antifungals used to treat fungal infections such as; ketoconazole, itraconazole, voriconazole, fluconazole
- aprepitant, a medicine used to treat nausea and vomiting
- medicine used to treat high blood pressure and other heart problems such as; diltiazem, verapamil

How to use BLEPHAMIDE®:

- Shake the bottle well before using.
- If you wear contact lenses, you should not wear them while you are using **BLEPHAMIDE®**.
- Be careful not to touch your eye or any other surface with the tip of the bottle. If you do, you may contaminate the medicine and this can infect your eyes later on.
- Although you may feel better early in treatment, **BLEPHAMIDE®** should be used exactly as directed.
- Misuse or overuse of **BLEPHAMIDE®** could lead to the growth of bacteria that will not be killed by sulfacetamide sodium (resistance). This means that **BLEPHAMIDE®** or other medicines that contain sulfacetamide sodium may not work for you in the future.
- Do not share your medicine.
- If your symptoms do not go away after two days of using **BLEPHAMIDE®**, talk to your healthcare professional. Your healthcare professional will need to decide if you should keep using **BLEPHAMIDE®**.

How to apply BLEPHAMIDE®:

Use one of the following methods to apply **BLEPHAMIDE®**. Your healthcare professional will tell you which method to use. Talk to your healthcare professional if you are not sure how to apply **BLEPHAMIDE®**.

METHOD I: In the Eye and On the Lid

1. Wash your hands well. Tilt your head back and put one drop into your eye.
2. Close your eye, and spread the excess medication, present after closing your eye, over the full length of your upper and lower lids.
3. Do not wipe any of the medication off your lids. It will dry completely in 4 or 5 minutes to a clear film. This clear film will remain on your lid for several hours and it will not interfere with your vision.
4. You should wash the medication off your lids once or twice daily. Then, you should reapply after each washing.

METHOD II: On the Lid Only

1. Wash your hands well. With your head tilted back and your eye closed, put one drop onto your lid preferably at the corner of your eye close to your nose.
2. Spread the medication over the full length of your 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 your lid for several hours.
4. You should wash the medication off your lids once or twice daily. Then, you should reapply after each washing.

Usual dose:

The usual dose is one drop for each affected eye 2 to 4 times a day.

Overdose:

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.

What are possible side effects from using BLEPHAMIDE®?

These are not all the possible side effects you may feel when taking **BLEPHAMIDE®**. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Altered sense of taste
- Dizziness (feeling faint or weak)
- Drooping of the eyelid
- Eye swelling
- Eye irritation
- Eye redness
- Eyelid swelling
- Eyelids redness
- Feeling like there is something in your eye
- Headache
- Hypersensitivity
- Itchy eyes
- Large (dilated) pupils
- Rash, itching around the eye

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reaction: difficulty breathing, difficulty swallowing, fever, hives, itchy skin, rash, swelling of your tongue, throat or face.			√
Cataracts (clouding of the lens of your eye): blurry vision, clouded vision, eye pain, fading or yellowing of colours, seeing halos and glare around lights, trouble seeing at night		√	
Eye infection, including corneal ulcers: itching, pain, redness, sensitivity to bright light, swelling, tearing, yellow discharge or crusts around the eye			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Glaucoma (serious eye disease where pressure in the eye is increased): blurred vision, eye redness, halos around lights, loss of vision, nausea, severe eye pain, vomiting			√
Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis (life-threatening skin conditions): blisters, rash, skin peeling, especially in mouth and eyes.			√
Cushings Syndrome: abnormal weight gain, bruising, fatigue, high blood pressure			√
Damage to a part of your eye called the optic nerve: vision loss			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

BLEPHAMIDE[®] should be stored at 15 to 25°C. Protect from freezing and light. Store in an upright position. Keep bottle tightly closed when not in use.

Keep out of reach and sight of children.

If you want more information about BLEPHAMIDE[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.allergan.ca, or by calling 1-800-668-6424.

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