

PRESCRIBING INFORMATION

DIOPTIMYD OINTMENT

**Sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.5% w/v
Sterile ophthalmic ointment**

Corticosteroid/ Antibacterial

Eberth Pharmaceuticas Inc,
56 Eastview Ave.,
Pointe-Claire, Québec H9R 5N6
Control No # 216068

Date of Revision :
May 3, 2019

PRESCRIBING INFORMATION

DIOPTIMYD OINTMENT

Sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.5% w/v

Corticosteroid / Antibacterial

ACTION AND CLINICAL PHARMACOLOGY

Prednisolone acetate is a potent synthetic corticosteroid with anti-inflammatory properties, useful in the treatment of inflammatory conditions of the eye, particularly the anterior segment. Corticosteroids suppress the inflammatory response to a variety of agents. Since they may inhibit the body's defense mechanism against infection, a concomitant antibacterial drug may be used when there is the risk of ocular infection. Corticosteroids probably also delay healing.

Sulfacetamide sodium is a sulfonamide with bacteriostatic action, except at very high concentrations as may occur with ophthalmic use, when it may be bactericidal. It interferes with the utilization of para-aminobenzoic acid by bacteria, thus preventing the essential biosynthesis of folic acid, and inhibiting growth of a wide variety of gram-negative and gram-positive bacteria. It is particularly suited to the eye because it is freely soluble in water and less alkaline, and therefore less irritating to the eye, than other sulfonamides.

INDICATIONS

For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or risk of bacterial 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 selected types of infective conjunctivitis when the inherent risk of steroid use is acceptable in order to obtain a diminution of edema and inflammation. Use in corneal injury from chemical, radiation and thermal burns or penetration of foreign bodies is also indicated.

The use of a combination drug with an antibacterial component is indicated where there is risk of infection. Sulfacetamide sodium, the particular antibacterial drug in Dioptimyd Ointment, is effective against many strains of the following organisms commonly found in eye infections: *S.aureus*, *Streptococci*, *E. coli*, *H. influenzae*, *Klebsiella*, and *Enterobacter* species.

A significant percentage of staphylococcal isolates are completely resistant to sulfa drugs. It is not effective against *Neisseria* species and *Serratia marcescens*

DIOPTIMYD OINTMENT contains an antibacterial ingredient, sulfacetamide sodium. To reduce the development of drug-resistant bacteria and maintain the effectiveness of sulfacetamide sodium, DIOPTIMYD OINTMENT should only be used for the authorized indication and clinical use.

CONTRAINDICATIONS

It is contraindicated if individual is hypersensitive to any of its components. Should not be used in the presence of viral diseases of the cornea and conjunctiva; tuberculosis of the eye; fungal disease 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.

WARNINGS

Prolonged use may result in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored.

In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids.

In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

Use of ocular steroid medication in the treatment of herpes simplex requires great caution.

PRECAUTIONS

Prolonged use may predispose to secondary fungal or bacterial ocular infection. Systemic adverse reactions may occur following prolonged use of steroids with occlusive dressings.

Dioptimyd Ointment is incompatible with silver solutions. Non-susceptible organisms may proliferate with the use of Sulfacetamide sodium. Sulfonamides are inactivated by the para-aminobenzoic acid present in purulent exudates. Sensitization may recur when a sulfonamide is re-administered irrespective of the route of administration, and cross-sensitivity between different sulfonamides may occur. If signs of hypersensitivity or other untoward reactions occur, discontinue use.

Susceptibility/Resistance

Development of Drug Resistant bacteria

Prescribing DIOPTIMYD OINTMENT in the absence of the 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 DIOPTIMYD OINTMENT may result in overgrowth of non-susceptible bacteria and fungi. If the infection is not improved following 2 days of treatment, cultures should be obtained to guide further treatment. If such infections occur, discontinue use and institute alternative therapy.

ADVERSE REACTIONS

Adverse effects observed with corticosteroid/antibacterial combination drugs can be attributed to the steroid component, the antibacterial or other ingredients.

Extended ophthalmic use of corticosteroid drugs may cause increased intraocular pressure in certain individuals and in those diseases causing thinning of the cornea, perforation has been known to occur. Posterior sub capsular cataract formation and delayed wound healing may also occur.

Dioptimyd Ointment may cause local irritation; transient burning and stinging may occur. Although sensitivity reactions to Sulfacetamide sodium rare, an isolated incident of Stevens-Johnson syndrome was reported in a patient who had experienced a previous bullous drug reaction to an orally administered sulfonamide and a single instance of local hypersensitivity was reported which progressed to a fatal syndrome resembling systemic lupus erythematosus.

DOSAGE AND ADMINISTRATION

A small amount of Dioptimyd Ointment 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.

AVAILABILITY

Dioptimyd Ointment contains: sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.5% w/v and the following non-medicinal ingredients: Lanolin alcohol, mineral oil, petrolatum and white petrolatum

STORAGE CONDITIONS

Dioptimyd Ointment 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.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

DIOPTIMYD OINTMENT

Sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.5% w/v

Read this carefully before you start taking **Dioptimyd Ointment** 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 **Dioptimyd Ointment**.

What is Dioptimyd Ointment used for:

Dioptimyd Ointment is used to treat inflammation in the eye and to treat or prevent bacterial infection.

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

How does Dioptimyd Ointment work?

Dioptimyd Ointment contains two medicines that work together to treat your eye:

- Prednisolone acetate is a corticosteroid that reduces inflammation.
- Sulfacetamide sodium is an antibiotic that kills and prevents the growth of bacteria to reduce infections.

What are the ingredients in Dioptimyd Ointment?

Medicinal ingredient: Sulfacetamide sodium and prednisolone acetate

Non-medicinal ingredients: Lanolin alcohol, mineral oil, petrolatum and white petrolatum

Dioptimyd Ointment comes in the following dosage forms:

Ophthalmic ointment, sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.5% w/v

Do not use Dioptimyd Ointment:

If you are allergic to Sulfacetamide sodium, prednisolone acetate or any of the ingredients in Dioptimyd Ointment. .

You should not use Dioptimyd Ointment if you have a viral or fungal eye infection, tuberculosis of the eye or any previous untreated eye infection.

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 Dioptimyd Ointment:

- Silver solutions.

How to take Dioptimyd Ointment:

- Misuse or overuse of Dioptimyd Ointment could lead to the growth of bacteria that will not be killed by sulfacetamide sodium (resistance). This means that Dioptimyd Ointment or other medicines that contain sulfacetamide sodium may not work for you in the future.
- Do not share your medicine.
- Avoid touching the tip of the tube with your finger or eye to avoid contamination. Put the cap back on after use.
- To apply the ointment:
 - Pull down your lower eye lid.
 - Apply a small amount of Dioptimyd Ointment inside your eyelid (conjunctival sac).
 - Blink to spread the medicine.

Dioptimyd Ointment, 1.0%:

A small amount of Dioptimyd Ointment should be applied to the conjunctival sac three or four times daily and once or twice at night. If your symptoms do not get better within 2 days, talk to your doctor.

Overdose:

If you think you have taken too much **Dioptimyd Ointment**, contact your healthcare professional, hospital emergency department or regional poison control center immediately, even if there are no symptoms.

What are possible side effects from using Dioptimyd Ointment?

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

Side effects include:

- Stinging or burning sensation
- Wounds taking longer to heal

| 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 | |
| Visions changes associated with glaucoma (increased eye pressure) and/or cataracts (clouding of the lens of the eye): hazy, blurry or dim vision, eye and head pain, swelling or redness in or around the eye. | | X | |
| Vision changes associated with corneal perforation (thinning or tearing of the front of the eye): | | | X |

| | | | |
|--|--|--|---|
| worsening of vision or loss of vision. | | | |
| Stevens-Johnson syndrome (severe skin and mucous membrane reaction): Blisters on your skin and around your eyes, fever, red or purple rash. | | | X |

Reporting Suspected 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](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-833-234-2345

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:

Dioptimyd Ointment should be stored at 15° to 25°C. Protect from freezing and light. Store in an upright position. Keep away from heat and light.

Inspect ointment before use. If the ointment is dark brown, discard.

Keep out of reach or sight of children.

If you want more information about Dioptimyd Ointment:

- Talk to your healthcare professional.
- Find the full prescribing information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>) or by calling 1-833-278-8556

This leaflet was prepared by Eberth Pharmaceuticals Inc.

Last Revised May 3, 2019