

PRESCRIBING INFORMATION

PrPREDNISOLONE/SULFACETAMIDE

**Sulfacetamide Sodium and Prednisolone
Acetate Ophthalmic Suspension, USP**

Corticosteroid / Antibacterial

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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.

NON-MEDICINAL INGREDIENTS

Benzalkonium Chloride 0.025%, Disodium Edetate. Hydroxypropyl Methylcellulose, Polysorbate 80, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Sodium Thiosulphate and Purified Water.

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 Prednisolone/Sulfacetamide, 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

Prednisolone/Sulfacetamide contains an antibacterial ingredient, sulfacetamide sodium. To reduce the development of drug-resistant bacteria and maintain the effectiveness of sulfacetamide sodium, Prednisolone/Sulfacetamide 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

The initial prescription and renewal of the medication beyond 20 ml of suspension should be made by a physician only after examination of the patient with the aid of magnification, such as slit-lamp bio-microscopy and, where appropriate, fluorescein staining. Systemic adverse reactions may occur following prolonged use of steroids with occlusive dressings.

Prednisolone/Sulfacetamide is incompatible with silver solutions. 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 Prednisolone/Sulfacetamide 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 may predispose to secondary fungal or bacterial ocular infection. Non-susceptible organisms may proliferate with the use of Sulfacetamide sodium. **A significant percentage of staphylococcal isolates are completely resistant to sulfa drugs.**

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.

Prednisolone/Sulfacetamide 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

Dosage should be adjusted to the specific needs of the patient. One or two drops topically in the conjunctival sac(s). In severe disease, drops may be used hourly, the dose being tapered to discontinuation as the inflammation subsides. In mild disease, drops may be used four to six times daily. Not more than 20 ml should be prescribed initially and the prescription should not be refilled without further evaluation as outlined in PRECAUTIONS above.

Patients should be advised to avoid contamination of the applicator tip during use and to replace the cap after use. Shake well before using (Cloudiness of this suspension is to be expected.).

AVAILABILITY

Prednisolone/Sulfacetamide contains: sulfacetamide sodium 10.0% w/v and prednisolone acetate 0.5% w/v and the following non-medicinal ingredients: Benzalkonium Chloride 0.025% as, Disodium Edetate. Hydroxypropyl Methylcellulose, Polysorbate 80, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Sodium Thiosulphate and Purified Water.

Prednisolone/Sulfacetamide Sterile Ophthalmic Suspension is supplied in 5 ml and 10 ml plastic squeeze bottles with an applicator tip.

STORAGE CONDITIONS

Store at controlled room temperature (15° - 30°C). Protect from freezing.

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

P^rPREDNISOLONE/SULFACETAMIDE

**Sulfacetamide Sodium and Prednisolone
Acetate Ophthalmic Suspension, USP**

Read this carefully before you start taking **Prednisolone/Sulfacetamide** 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 **Prednisolone/Sulfacetamide**.

What is Prednisolone/Sulfacetamide used for?

Prednisolone/Sulfacetamide is used to treat inflammation of the eye and prevent bacterial infection

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

How does Prednisolone/Sulfacetamide work?

Prednisolone is used to treat inflammation of the eye
Sulfacetamide is an antibacterial drug that prevents infections by stopping the growth of bacteria.

What are the ingredients in Prednisolone/Sulfacetamide?

Medicinal ingredient: Sulfacetamide sodium and prednisolone acetate

Non-medicinal ingredients: Benzalkonium Chloride 0.025%, Disodium Edetate. Hydroxypropyl Methylcellulose, Polysorbate 80, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Sodium Thiosulphate and Purified Water.

Prednisolone/Sulfacetamide comes in the following dosage forms:

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

Prednisolone/Sulfacetamide Sterile Ophthalmic Suspension is supplied in 5 ml and 10 ml plastic squeeze bottles with an applicator tip.

Do not use Prednisolone/Sulfacetamide Ointment if you:

- Are allergic to prednisolone, sulfacetamide or any of the ingredients in **Prednisolone/Sulfacetamide** Ointment.
- Have an eye infection. **Prednisolone/Sulfacetamide** may hide or worsen certain infections

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

- Any eye conditions.
- Are allergic to any other antibiotics.

Warnings that you should know about:

Prednisolone/Sulfacetamide may cause glaucoma (increased pressure in the eye). Your doctor may monitor your eye pressure if you are taking **Prednisolone/Sulfacetamide** for long periods of time.

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 Prednisolone/Sulfacetamide:

- Silver solutions.

How to take Prednisolone/Sulfacetamide:

- Misuse or overuse of **Prednisolone/Sulfacetamide** could lead to the growth of bacteria that will not be killed by sulfacetamide sodium (resistance). This means that **Prednisolone/Sulfacetamide** 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 applicator with your finger or eye to avoid contamination.* Put the cap back on after use.
- *Shake the bottle well before using.*
- To apply the drops:
 - Pull down your lower eye lid
 - Instill 1 – 2 drops inside your eyelid (conjunctival sac)

Usual Adult Dose:

Your doctor will tell you how much **Prednisolone/Sulfacetamide** you should take. Depending on your condition, you may need to take 1 - 2 drops 4 – 6 times daily.

Overdose:

If you think you have taken too much **Prednisolone/Sulfacetamide**, 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 Prednisolone/Sulfacetamide?

These are not all the possible side effects you may feel when taking **Prednisolone/Sulfacetamide**. 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		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): worsening of vision or loss of vision.			X
Stevens-Johnson syndrome (severe skin and mucous membrane reaction): Blisters on your skin and around your eyes, fever, red or purple rash.			X

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 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 1-866-234-2345.

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:

Store at controlled room temperature (15° - 30°C). Protect from freezing.

If you want more information about Prednisolone/Sulfacetamide:

- 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:

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