SULMAD EYE DROPS

Sulfacetamide Sodium USP 100mg
Prednisolone acetate USP 2mg
Phenylephrine HCl USP 1.2mg

Sterile Ophthalmic Suspension

سل میڈ

سلف ایسٹ امائیڈسوڈیم ۱۰۰ ملی گرام
پریڈنیسلون ایسیٹیٹ ۲ ملی گرام
فینی لیفرین ہائیڈروکلورائیڈ ۱.۲ ملی گرام
آنکھوں کے لئے قطرے جراثیم سے پاک

۵ ملی لیٹر (تقریباً) آنکھوں کے قطرے

۵ ملی لیٹر (تقریباً) آنکھوں کے قطرے

COMPOSITION:

Sulphacetamide Sodium .....100mg.
Prednisolone acetate .....2mg.
Phenylephrine HCL.....1.2mg.

ACTION:

Sulphacetamide sodium at 10% concentration is a potent bacteriostatic agent (effective against a broad range of pathogens, including Staphylococci). The prednisolone content (in microfine, non-irritating suspension) effectively counters the allergic and inflammatory manifestations of blepharitis. The Phenylephrine components rapidly whitens the engorged vessels in the eye and lid.

INDICATIONS:

SULMAD is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. The anti-infective drug in this product, sulfacetamide, is active against the following common bacterial eye pathogens: Escherichia coli, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus (viridans group), Haemophilus influenzae, Klebsiella species, and Enterobacter species. This product does not provide adequate coverage against Neisseria species, Pseudomonas species and Serratia marcescens. A significant percentage of staphylococcal isolates are completely resistant to sulfa drugs.

DOSAGE:

1-2 drops in the affected eye(s) 3 to 4 times a day.

CONTRAINDICATIONS:

SULMAD is contraindicated in:
most viral diseases of the cornea and conjunctiva, including superficial (or epithelial) herpes simplex keratitis (dendritic keratitis), - vaccinia, and varicella mycobacterial infection of the eye fungal diseases of ocular structures patients with known or suspected hypersensitivity to Sulfonamides, other corticosteroids, or to any component of this product.

PRECAUTIONS AND WARNINGS:

SEVERE REACTIONS

Fatalities have occurred, although rarely, due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulmjnant 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. At the first sign of hypersensitivity, skin rash, increase in purulent discharge' or aggravation of inflammation or pain, the patient should discontinue use of the medication and consult a physician. Cross-sensitivity between different sulfonamides or between corticosteroids may occur.
SULMAD suspension contains the preservative phenylmercuric nitrate, which may cause allergic-type reactions in susceptible patients.

POTENTIAL EFFECTS OF PROLONGED USE

Prolonged use of topical anti-bacterial agents may give rise to overgrowth of non susceptible organisms including fungi. Bacterial resistance to Sulfonamide's may also develop. A significant percentage of staphylococcal isolates are completely resistant to sulfa drugs.
Prolonged use of corticosteroids may increase Intraocular pressure in susceptible individuals, resulting in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the Presence of glaucoma intraocular pressure should be checked frequently.
Prolonged use may result in Posteriod subcapsular cataract formation.
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 intraocular pressure.

CORNEAL AND SCLERAL THINNING

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

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 also suppress the host immune response and thus increase the hazard of secondary ocular infections. As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. 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.

DELAYED HEALING AND BLEB FORMATION

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

POTENTIAL FOR EYE INJURY OR CONTAMINATION

To prevent eye injury or contaminating the dropper tip and suspension, do not touch the eyelids, the surrounding area or any surface with the dropper tip of the bottle.

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.

USE WITH CONTACT LENSES

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

DRUG INTERACTIONS

The effectiveness of Sulfonamide's may be reduced by the Para aminobenzoic acid present in purulent exudates and certain local anesthetics that are esters of p-aminobenzoic acid. SULMAD is incömpatible with silver preparations.

USE IN PREGNANCY AND LACTATION PREGANCY

Animal studies have not been conducted with sulfonamide ophthalmic preparations.
Prednisolone has been shown to be teratogenic in rabbits, hamsters and mice. In mice, prednisolone has been shown to be teratogenic when given in doses 1 to 10 times human ocular dose. Dexamethasone, hydrocortisone and prednisolone were ocularly applied to both eyes of pregnant mice five times per day on days 10 through 13 of gestation. A significant increase in the incidence of cleft palate was observed in the fetuses of the treated mice, Kernicterus may be precipitated in infants by sulfonamides being given systemically during the third trimester of pregnancy. There are no adequate and well controlled studies of SULMAD in pregnant women, and it is not known whether SULMAD can cause fetal harm when administered to a pregnant woman.
SULMAD 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.

LACTATION

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 SULMAD, a decision should be made whether to discontinue nursing or to discontinue the medication.

PEDIATRIC USE

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

GERIATRIC USE

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

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.

ADVERSE REACTIONS:

The following adverse reactions have been identified during post approval use of SULMAD. 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 SULMAD 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).
The reactions due to the corticosteroid component in decreasing order of frequency are: elevation of intraocular pressure (LOP) 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 SUPPLIED:

As 5 ml sterile ophthalmic suspension in plastic dropper bottle.

Storage Conditions:

Store below 15°C to 25°C. Protect from light and moisture. Keep out of reach of children. Use only on medical advice. For Ophthalmic use only. Once opened use within one month. Shake well before use.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: دھوپ اور نمی سے بچائیں۔
ٹھنڈی اور خشک جگہ پر رکھیں۔
درجہ حرارت کی حد ۱۵ سے ۲۵ سینٹی گریڈ ہے۔
اختتام: پہلی دفعہ بوتل کھولنے کے بعد دوا کو ایک ماہ
تک استعمال کیا جاسکتا ہے۔ استعمال کرنے سے پہلے بوتل اچھی طرح ہلالیں۔
صرف آنکھوں کے استعمال کے لئے۔
بچوں کی پہنچ سے دور رکھیں۔

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