1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS:

S2

1. NAME OF THE MEDICINE

LENNON SULPHACETAMIDE EYE OINTMENT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3,5 g ointment contains 350 mg sulphacetamide sodium.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

LENNON SULPHACETAMIDE EYE OINTMENT is a beige ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

LENNON SULPHACETAMIDE EYE OINTMENT is indicated in adults for treatment of infections of the eye and eye socket, sties and trachoma.

4.2. Posology and method of administration

Posology

LENNON SULPHACETAMIDE EYE OINTMENT is usually applied as a thin strip into the conjunctival sac of the infected eye every 6 hours and at bedtime.

Consult your doctor if no improvement has occurred within 6 days.

Paediatric population

No data are available.

Method of administration

Topical

4.3. Contraindications

LENNON SULPHACETAMIDE EYE OINTMENT is contraindicated in:

- Patients with hypersensitivity to sulphacetamide sodium, sulphonamides or to any excipients in LENNON SULPHACETAMIDE EYE OINTMENT (see section 6.1).
- The application to penetrating wounds of the cornea.
- Concurrent administration with preparations containing silver salts.

4.4. Special warnings and precautions for use

Treatment with sulphonamides should be stopped immediately when a rash appears because of the danger of severe allergic reactions such as the Stevens-Johnson syndrome.

Patients with glucose 6-phosphate dehydrogenase deficiency may be at risk of haemolytic reactions.

Sulphonamides have been associated with acute attacks of porphyria and are considered unsafe in porphyric patients.

It should be used with caution in patients with dry-eye syndrome.

Caution is also needed in the elderly, who may be more likely to have other risk factors for adverse reactions.

Sulphonamides have been reported to interfere with some diagnostic tests, including those for urea, creatinine, and urinary glucose and urobilinogen.

Local application to the eye may cause burning or stinging, but this is rarely severe enough to necessitate discontinuance of treatment.

Patients sensitive to furosemide, thiazide diuretics, sulphonylureas, or carbonic anhydrase inhibitors may be sensitive to sulphonamides also.

Paediatric population

Daytime use of LENNON SULPHACETAMIDE EYE OINTMENT is not advocated in children over one year of age because it may temporarily interfere with vision.

4.5. Interaction with other medicines and other forms of interaction

Silver preparations

Silver preparations such as silver nitrate or mild silver protein (see section 4.3)

Oral anticoagulants (warfarin), methotrexate and phenytoin:

The effects of these medications may be potentiated due to the displacement of the medicine from plasma binding sites or to inhibition of metabolism.

4.6. Fertility, pregnancy and lactation

The safety and efficacy during pregnancy and lactation has not been established.

Fertility

No data available.

4.7. Effects on ability to drive and use machines

LENNON SULPHACETAMIDE EYE OINTMENT has moderate influence as it may cause blurred vision and should be used with caution if driving or operating machinery.

4.8 Undesirable effects

System organ class	Frequent	Less frequent	Frequency unknown
Eye disorders			Blurred vision, burning and stinging
Respiratory, thoracic and mediastinal disorders			Nasal irritation
Gastrointestinal disorders			Bitter taste, unpleasant sensation in the throat
Skin and subcutaneous tissue disorders	Hypersensitivity reactions including itching, redness, swelling, or other signs of irritation not present before therapy (see section 4.4)		

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088 /+27 (0)11 239-6200

4.9 Overdose

Symptoms

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

Treatment

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class: A 15.1 Ophthalmic preparations with antibiotics and/or sulphonamides

Pharmacotherapeutic group: Ophthalmological, Anti-infectives, Sulphonamides

ATC Code: S01AB04

Mechanism of action

Sulphacetamide has a similar structure to p-aminobenzoic acid and interferes with the synthesis of nucleic acids in sensitive micro-organisms. Its action is primarily bacteriostatic and broad spectrum.

Sulphacetamide sodium is used extensively in the management of ophthalmic infections susceptible to sulphonamides.

Its use in chronic and acute conjunctivitis is well established.

5.2. Pharmacokinetic properties

Absorption

When sulphacetamide sodium is applied to the eye it penetrates into ocular tissues and fluids and may be absorbed into the blood when the conjunctiva is inflamed.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Liquid paraffin, yellow soft paraffin.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25 ºC in airtight containers.

Protect from light.

Do not freeze.

FOR EXTERNAL USE ONLY.

Discard 30 days after first opening.

Keep in original packaging until required for use.

6.5. Nature and contents of container

3,5 g is packed in an aluminium collapsible tube, with a white high-density polyethylene self-piercing cap. The tube is placed in a unit cardboard carton together with a leaflet.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBER:

H1169 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION

27 May 1999

10. DATE OF REVISION OF TEXT

31 January 2025

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088

Botswana: B9322905 S3

Namibia: NS1 14/15.1/0610

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