SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT :

Neopred

2. QUANTITATIVE AND QUALITATIVE COMPOSITION:

Component	Composition
Prednisolone sodium phosphate	27,5 mg
Neomycin sulfate	17,5 mg

Excipients Qsf 5 ml.

3. PHARMACEUTICAL FORM:

5 ml eye drops bottle.

4. CLINICAL DATA:

4.1. THERAPEUTICAL INDICATIONS:

- Inflammation and allergy with microbial component of the anterior segment of the eye.
- Uveitis,
- Scleritis,
- Episcleritis,
- Allergic conjunctivitis
- Interstitial keratitis.

4.2. DOSAGE AND METHOD OF ADMINISTRATION:

One drop in the lower conjunctival sac every hour at the start of treatment in severe acute conditions, 3 to 6 times per day in other cases, for 7 days on average.
Longer treatment or more frequent instillations may be prescribed under strict ophthalmological supervision.

4.3. CONTRAINDICATIONS:

- intraocular hypertension
- Hypersensitivity to any component of the medication.
- Epithelial dendritic herpetic keratitis.
- Personal or family history of glaucoma.
- Mycotic or tuberculous infections of the eye.
- Early stage viral keratoconjunctivitis.
- Purulent infections of the eyelids and eye secondary to germs resistant to neomycin.

4.4. SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE:

- The benefits of local corticosteroid therapy must be carefully weighed against the possible complications with such treatment.
- As the systemic effects are very weak during local administration of corticosteroids, it is unlikely that patients treated with Neopred at the recommended dosage will develop the adverse effects encountered with oral or parenteral corticosteroid treatment. However, it is possible that an individual may have a hypersensitivity to corticosteroids or may use them beyond the recommended dose; in this case, we must be vigilant about the appearance of adverse effects linked to corticosteroids.
- As with all other corticosteroids, prolonged local application (1 to 2 weeks or more) of Prednisolone in the eye may lead to an increase in intraocular pressure. In case of prolonged use of this eye drop, the intraocular pressure should be checked regularly.
- This type of association is generally contraindicated after simple removal of a superficial corneal foreign body.
- The use of corticosteroids in the treatment of stromal herpes simplex requires very careful monitoring; a slit lamp examination is frequently required.
- In patients treated for a prolonged or repeated period with this type of eye drops, a regular examination of the eye will be carried out and will include a particularly careful clinical evaluation of the cornea and lens; There have been reports of corneal thinning and cataracts after prolonged treatment with certain topical corticosteroids.
- Viral, bacterial and fungal infections of the eye can be activated, exacerbated or masked by the application of corticosteroids. If the infection does not resolve quickly, Neopred should be stopped until the infection is adequately controlled. As fungal infections of the cornea have a predisposition to develop during prolonged local application of corticosteroids, they should be sought in the face of persistent corneal ulceration in patients who have been treated, or are still under treatment with corticosteroids.
- Neomycin sulfate can sometimes cause skin sensitization; in this case, the administration of the medicine must be stopped.
- Hereditary and degenerative eye diseases generally do not respond to treatment with this type of medication.
- In the absence of rapid improvement or in case of prolonged treatment, regular medical monitoring including bacteriological checks with study of the sensitivity of the germ makes it possible to detect resistance to the medicine and possibly adapt the treatment.
- The eye drops should not be used as a peri- or intraocular injection.
- If concomitant treatment with eye drops containing a different active ingredient, instill the eye drops 15 minutes apart.
- Use of the medication should be avoided in infants.
- Wearing lenses should be avoided during treatment due to the risk of absorption.

4.5. INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS:

No significant interactions.

4.6. PREGNANCY AND BREASTFEEDING:

In pregnant or breastfeeding women, use with caution under strict medical supervision.

4.7. EFFECTS ON THE ABILITY TO DRIVE VEHICLES AND USING MACHINES

Not applicable.

4.8. SIDE EFFECTS:

- Possibility of transient local irritation: discomfort, tearing, burning, conjunctival hyperemia.
- Risk of cutaneous-conjunctival hypersensitivity reaction (e.g. type of edema).
- Increased ocular tone with possible development of glaucoma.
- Delayed healing.
- With prolonged use: corticosteroid-induced ocular hypertension, opacification of the lens, superficial keratitis.
- In case of corneal or scleral ulceration, corticosteroids may delay healing and promote superinfection.
- In pathologies responsible for thinning of the cornea or sclera, it has been reported that perforations have occurred during the use of local corticosteroids.

4.9. OVERDOSAGE:

Repeated instillations can induce systemic passage of the corticosteroid.

5. PHARMACOLOGICAL PROPERTIES:

5.1. PHARMACODYNAMIC PROPERTIES:

Prednisolone sodium phosphate is a steroidal anti-inflammatory drug.
Neomycin sulfate is a bactericidal antibiotic from the aminoglycoside family.

6. PHARMACEUTICAL DATA:

6.1. INCOMPATIBILITIES:

No significant incompatibility.

6.2. SHELF LIFE:

24 months from the manufacturing date.

6.3. SPECIAL PRECAUTIONS FOR STORAGE:

Keep away from light and heat.
Any opened bottle must be used within 15 days.

6.4. NATURE AND CONTENT OF THE OUTER PACKAGING:

Box of one low-density polyethylene bottle, with dropper and tamper-proof caps.

7. MARKETING AUTHORIZATION HOLDER:

LES LABORATOIRES MEDIS-S.A.
Road of Tunis - KM 7 - BP 206 - 8000
Nabeul - Tunisia
Tel: (216) 72 23 50 06
Fax: (216) 72 23 51 06
E-mail: marketing.ventes@medis.com.tn

8. PRESCRIPTION AND SUPPLY CONDITIONS:

List I.

9. PRESENTATION AND ADMINISTRATIVE IDENTIFICATION NUMBER:

NEOPRED, eye drops Bottle of 5 ml.

M.A N° country of origin : 9233251

10. DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION

Date of obtaining M.A: 19/06/2002
Date of first MA renewal: 19/06/2007
Date of second MA renewal: 19/06/2012
Date of third MA renewal: 19/06/2017
Date of fourth MA renewal: 19/06/2022

11. DATE OF TEXT UPDATE:

06/2022