

Hypotears® eye gel

COMPOSITION

Active substance: Retinol palmitate

Excipients: Carbomer 980, cetrimide as preservative, gel excipients to 1 g

PHARMACEUTICAL FORM AND QUANTITY OF ACTIVE SUBSTANCE PER UNIT

Hypotears® eye gel: Retinol palmitate, 1000 IU/g

INDICATIONS/POTENTIAL USES

As adjuvant therapy for corneal protection in:

- Dry eye of varying pathogenesis (e.g. Sjögren's syndrome, neuroparalytic keratitis, exposure keratitis).

Irritation of the conjunctiva and cornea due to deficient tear film protection.

DOSAGE AND ADMINISTRATION

Adults

Depending on individual requirements, usually one drop three times daily to one drop hourly.

To date, use and safety in children and adolescents have not been systematically investigated.

CONTRAINDICATIONS

Hypersensitivity to any of the components of Hypotears.

WARNINGS AND PRECAUTIONS

Note for contact lens wearers

Hypotears should not be applied while contact lenses are being worn. Lenses should be removed before administration and should not be reinserted until at least 30 minutes have elapsed.

INTERACTIONS

If another eye medication is used, it should be applied at least 5–10 minutes before Hypotears. Hypotears should always be applied last.

PREGNANCY AND LACTATION

There have been no controlled studies in animals or pregnant women. Caution is therefore required when using the medicinal product in patients who are pregnant or breastfeeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Vision may be blurred for a short time following application. This should be borne in mind when using machines or driving.

ADVERSE EFFECTS

A mild sensation of burning may occur for a short time following application. Hypersensitivity reactions may also occur.

OVERDOSE

No case of overdose has been reported.

PROPERTIES AND ACTIONS

Mechanism of action – pharmacodynamics – clinical efficacy

Due to its long retention time, Hypotears eye gel is suitable for use as a tear substitute both in cases of deficient tear secretion, and in forms of "dry eye" in which the tear film is unstable due to the poor quality of the tears and the hypersecretion thus induced.

Increased viscosity strengthens the protective colloid effect through physical lubrication. The addition of vitamin A, which counteracts signs of dehydration in the corneal epithelium, reinforces the therapeutic effect.

Vitamin A (retinol) is necessary for the normal differentiation of epithelial cells. Retinol deficiency leads to a lack of goblet cells, atrophy of the epithelial cells and proliferation of conjunctival basal cells.

PHARMACOKINETICS

Good corneal penetration by topically applied retinol has been demonstrated in the healthy rabbit eye. No statement can be made on the extent of penetration, or on distribution and retention, in the human eye.

PRECLINICAL DATA

No product-specific data of relevance for use are available.

OTHER INFORMATION

Shelf-life

When stored unopened, Hypotears® eye gel may be used until the expiry date (= EXP) printed on the pack and tube. After opening, do not use for more than 1 month.

Special precautions for storage

Before being opened the first time, Hypotears gel must be stored in a refrigerator (2–8°C). After being opened the first time, Hypotears remains stable at room temperature (15–25°C) for 30 days.

Instructions for use and handling

Close the tube immediately after use. Do not touch the nozzle.

PACK SIZES

Country specific pack sizes.

MANUFACTURER

See folding box.

Information last revised : December 2003

Approval date (text) : 15 January 2004

® = registered trademark

Novartis Pharma AG, Basle, Switzerland

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists