NOVARTIS

Drug Regulatory Affairs

HYPOTEARS®GEL

(retinol palmitate)

Eye gel

International Package Leaflet

(This IPL is based on Reference Labelling document for Prescribers dated 22 Jun 2010)

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HypoTears® Gel

Vitamin A (retinol) palmitate

COMPOSITION AND PHARMACEUTICAL FORM

Retinol palmitate, 1,000 IU/g.

Eye gel.

For a full list of excipients, see section EXCIPIENTS.

INDICATIONS

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.

Hypotears gel contains a sterile solution until the original closure is broken. The tip of the container should not come into contact with any surface as this may contaminate the solution. It should also not come into contact with the eye as this may cause injury to the eye.

CONTRAINDICATIONS

Known hypersensitivity to retinol palmitate or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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 to 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.

UNDESIRABLE EFFECTS

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

The following adverse reactions have been reported from post-marketing experience. The reporting frequency cannot be estimated from the available data and is therefore "not known".

Immune system disorders

Localized hypersensitivity reactions.

Eye disorders

Eye irritation, transient blurred vision, ocular hyperaemia.

OVERDOSE

No case of overdose has been reported.

PHARMACODYNAMICS

Mechanism of action – pharmacodynamics – clinical efficacy

Due to its long retention time, Hypotears 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 SAFETY DATA

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

EXCIPIENTS

Carbomer 980, cetrimide as preservative, gel excipients to 1 g.

Pharmaceutical formulations may vary between countries.

INCOMPATIBILITIES

Not known.

STORAGE

See folding box.

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

Hypotears gel should not be used after the date marked "EXP" on the pack.

INSTRUCTIONS FOR USE AND HANDLING

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

Note: Hypotears gel must be kept out of the reach and sight of children.

Manufacturer:

See folding box.

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