NOVARTIS

Drug Regulatory Affairs

HYPOTEARS® LUBRICANT
HYPOTEARS® LUBRICANT PF (Preservative Free)

(1% w/v polyvinyl alcohol and 1% polyethylene glycol 400)

Eye drops

Basic Prescribing Information

NOTICE

The Basic Prescribing Information (BPI) is the Novartis Core Data Sheet. It displays the company's current position on important characteristics of the product, including the Core Safety Information according to ICH E2C.

National Prescribing Information is based on the BPI. However, because regulatory requirements and medical practices vary between countries, National Prescribing Information (incl. US Package Insert or European SPCs) may differ in several respects, including but not limited to the characterisation of risks and benefits.

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GLC approval:	07 December 1999, amended 15 July 2008, 20 January 2009 and 27 October 2009
Release date:	5 November 2009
Tracking Number:	2009-PSB/GLC-0230-s
Document status:	Final
Number of pages:	5

1 Name of the medicinal product

HYPOTEARS®

HYPOTEARS® PF (Preservative Free, Single Dose Units, (SDU))

2 Qualitative and quantitative composition

Hypotears® and Hypotears® PF contain 1% w/v polyvinyl alcohol and 1% polyethylene glycol 400.

For a full list of excipients, see section 6.1 List of excipients.

3 Pharmaceutical form

Eye drops.

Information might differ in some countries.

4 Clinical particulars

4.1 Therapeutic indications

For the temporary relief of burning and irritation due to dryness of the eye or to exposure to wind or sun. Helps protect against further eye irritation.

4.2 Posology and method of administration

Adults:

One or two drops in the affected eye(s) as required.

The dispenser 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 [5].

Elderly and children:

No dosage amendment is necessary in the elderly or in children.

4.3 Contraindications

Hypotears

Known hypersensitivity to benzalkonium chloride or to any excipients.

Hypotears PF, SDU

Known hypersensitivity to any of the excipients.

4.4 Special warnings and precautions for use

If eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours Hypotears must be discontinued and a doctor should be consulted.

If solution changes colour or becomes cloudy, do not use.

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. Replace cap after using. Discontinue use if allergy develops to any component of the preparation.

Keep this medicinal product out of the reach of children.

Hypotears contains benzalkonium chloride as a preservative. Benzalkonium chloride may cause eye irritation and is known to discolour soft contact lenses. Therefore, Hypotears should not be used while wearing lenses. The lenses should be removed before application of the drops and not reinserted earlier than 15 minutes after use.

Do not use if tamper resistant seal on bottle neck is broken or missing at time of purchase.

Hypotears PF: Discard immediately after use.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There is no experience regarding the safety of Hypotears eye drops in human pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Temporarily blurred vision may affect the ability to drive and use machines. If blurred vision occurs, the patient should wait until vision clears [3].

4.8 Undesirable effects

The following adverse events have been reported with Hypotears: Transient eye pain, eye irritation, ocular hyperaemia [2], eye swelling [2], eyelid oedema [2], eye pruritus [2], increased lacrimation [4] and temporarily blurred vision [3].

4.9 Overdose

Not applicable.

5 Pharmacological properties

5.1 Pharmacodynamic and pharmacokinetic properties

Pharmacotherapeutic group: artificial tears, ATC code. S01XA.

There are no pharmacologically active constituents in Hypotears. The action of polyvinyl alcohol in the eye is based on its demulcent and lubricating properties rather than chemical or pharmacological actions. In dry eye, often the tear fluid is characterised by an increased osmolarity, that can be a source of ocular surface suffering [1]. Hypotears normalizes the pre-corneal tear film by balancing tear film osmolarity and stabilizes the mucin and aqueous tear layers. The polyvinyl alcohol contained in Hypotears has mucomimetic properties to soothe and lubricate the dry eye and enhance tear film stability. Polyvinyl alcohol also reduces the surface tension of the tears to increase the wetting of the cornea by the tear film.

5.2 Preclinical safety data

The constituents of Hypotears and Hypotears PF have been used safely for many years.

6 Pharmaceutical particulars

6.1 List of excipients

Hypotears

Benzalkonium chloride (preservative), disodium edetate, glucose, anhydrous, water for injection, adjusted to pH with NaOH.

Hypotears PF, SDU

Disodium edetate, glucose, anhydrous, water for injection, adjusted to pH with NaOH.

Information might differ in some countries.

6.2 Incompatibilities

See Section 4.4 for information on the use of this product with soft contact lenses.

6.3 Shelf life

Hypotears

Unopened: 36 months

Opened: 4 weeks

Information might differ in some countries.

Hypotears PF, SDU

Unopened: 24 months

Opened: Discard immediately after use.

Information might differ in some countries.

6.4 Special precautions for storage

Do not store above 25°C.

Information might differ in some countries.

Hypotears and Hypotears PF SDU must be kept out of the reach and sight of children.

6.5 Nature and contents of container

Hypotears

Low Density Polyethylene (LDPE) bottles.

10, 15 and 30 mL

Country specific.

Hypotears PF, SDU

0.4 mL.

Country specific.

6.6 Instructions for use and handling

None.