NOVARTIS

Hypotears® Plus / Hypotears® Plus SDU eye drops

Composition
Active substances
Povidone K25, sodium chloride, sodium lactate, potassium chloride, calcium chloride, magnesium chloride

Excipients
Hypotears Plus
0.05 mg benzalkonium chloride per ml, vehicle excipients

Hypotears SDU
Vehicle excipients

Pharmaceutical form and quantity of active substance per unit
Hypotears Plus, Hypotears Plus SDU
Eye drops: 50 mg povidone per ml

Indications / Potential uses
Hypotears Plus
Symptomatic treatment of dry eye syndrome

Hypotears Plus SDU
Symptomatic treatment of dry eye syndrome, lubrication of hard (flexible) and soft (hydrophilic) contact lenses.

Dosage and Administration
Hypotears Plus / Hypotears Plus SDU eye drops are intended for use in adults. Their use and safety in children have not yet been studied.

Hypotears Plus / Hypotears Plus SDU
For symptomatic treatment of dry eye syndrome: Instil 1 drop into the eye as needed. It is normally sufficient to instil 1 drop four times daily.

Hypotears Plus SDU
For contact lens lubrication, instil 1 drop as needed either into the conjunctival sac, or onto the contact lens. One SDU (single-dose unit) suffices for the lubrication of both lenses.
Dry eye is often treated for prolonged periods. Such long-term treatment must be monitored regularly.

Contraindications
Hypersensitivity to the ingredients of Hypotears Plus / Hypotears Plus SDU.

Warnings and Precautions
Note for contact lens wearers: Multidose units of Hypotears
This product must not be used with soft (hydrophilic) contact lenses (risk of discoloration of contact lenses by absorption).

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

Pregnancy and Lactation
There have been no reproductive toxicity studies in animals, and there are no available controlled studies in pregnant women. Hypotears Plus / Hypotears Plus SDU should therefore be used with caution during pregnancy.
No data are available on the exposure of neonates to Hypotears Plus / Hypotears Plus SDU, and the product should therefore not be used by women who are breastfeeding.

Effects on ability to drive and use machines
If vision is blurred after instillation of Hypotears, patients should refrain from driving or from operating machinery.

Adverse effects
Eye disorders
A mild burning sensation and feeling of stickiness may briefly occur immediately after instillation. In rare cases, there may also be irritation or hypersensitivity reactions to one of the ingredients. There may be brief blurring of vision.

Overdose
No cases of overdose have been reported.

Properties and Actions
ATC code: S01 XA20

Mechanism of action
Hypotears contains povidone, a synthetic, water-soluble polymer of varying chain length. It also contains the electrolytes sodium, potassium, magnesium and calcium in quantities similar to those found in lacrimal fluid.
The surface of the cornea is moistened in particular by means of mucin produced in the conjunctiva. This mucin is adsorbed on the surface of the cornea, where it forms a hydrophilic layer. In patients with dry eye syndrome, the tear film is disrupted prematurely during non-blinking intervals, usually due to inadequate tear secretion or inadequate mucin production. This may lead to severe subjective symptoms. Hypotears permits partial compensation of tear film deficiencies by virtue of the protective film formed by povidone.

Pharmacokinetics
Absorption
The pharmacokinetics of Hypotears Plus and Hypotears Plus SDU have not been investigated either in humans or in animals. Povidone K25 is unlikely to penetrate the cornea due to its high molecular weight.

Preclinical data
Rats who had 5 or 10% PVP K25 (povidone) added to their feed for two years showed no toxic effects. No data are available on mutagenicity or teratogenicity.

Other information
Incompatibilities
High salt concentrations, e.g. of sodium sulphate under cold conditions or sodium chloride under warm conditions, may cause precipitation of povidone.

Shelf-life
When stored unopened, Hypotears Plus eye drops may be used until the expiry date (= EXP) printed on the pack and on the bottle or SDU.

Special precautions for storage
See folding box

Instructions for use and handling
Hypotears Plus (in bottle)
Close the dropper bottle immediately after use. Do not touch the dropper tip. After opening, do not use for more than 1 month.

Hypotears Plus SDU
Use immediately after opening the single-dose unit because this formulation contains no preservatives. For microbiological reasons, any eye drops left over in the opened single-dose unit after instillation should not be used. Discard opened single-dose units after use.

Pack sizes
Country specific pack sizes

Information last revised
November 2005

Approval date (text)
15 June 2006

Manufacturer
See folding box

® = 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

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Council of Arab Health Ministers
Union of Arab Pharmacists

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