1. NAME OF THE MEDICINAL PRODUCT

Hyprosan 3.2 mg/ml eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains 3.2 mg hypromellose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
Clear, colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Substitute for natural tears for the treatment of dry eyes, including keratoconjunctivitis sicca, in adults

4.2 Posology and method of administration

Posology
1 drop in each eye three times a day, or as needed.

Paediatric population
The safety and efficacy of Hyprosan in children and adolescents aged less than 18 years have not been established.

Method of administration
To avoid washout, Hyprosan should always be administered at least five minutes after any other ocular medications have been applied to the eyes.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

None.
Hyprosan does not contain any preservative, thus it can be used together with contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to hypromellose is negligible.
Hyprosan can be used during pregnancy.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to hypromellose is negligible.
Hyprosan can be used during breastfeeding.

Fertility
No effects on fertility are anticipated since systemic exposure to hypromellose is negligible.

4.7 Effects on ability to drive and use machines

Hyprosan has minor influence on the ability to drive and use machines, as it may cause transient blurred vision after administration.

4.8 Undesirable effects

The following adverse events have been reported with hypromellose solution:

Eye disorders:
Uncommon (≥1/1,000 to <1/100)
Local burning, eye pain and blurred vision

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

No known reactions.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Other ophthalmologicals
ATC code: S01XA20

Mechanism of Action
Hyprosan is a substitute for natural tears and does not contain any substances with a pharmacological effect.

5.2 Pharmacokinetic properties

Hypromellose increases the viscosity of Hyprosan. This results in an increased retention and moisturisation time on the eye.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

disodium phosphate dodecahydrate
sodium dihydrogen phosphate dihydrate
sodium hyaluronate
sodium chloride
water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened container: 2 years.
Opened container: 4 weeks.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.
For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Transparent plastic (LDPE) bottle and white dropper applicator of HDPE and silicone, with a blue tip and white HDPE cap.

Hyprosan is available in packages with 1 or 3 bottle(s) containing 10 ml of solution.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Santen Oy
Niittyhaankatu 20
FI-33720 Tampere
Finland

8 MARKETING AUTHORISATION NUMBER

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 November 2012
Date of latest renewal: *<To be completed nationally>*

10 DATE OF REVISION OF THE TEXT

2017-11-09