

Summary of Product Information

1. NAME OF THE MEDICAL DEVICE

HYLO NIGHT®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Retinol palmitate 250 I. U. / g

White vaseline, light liquid paraffin, liquid paraffin, wool fat.

3. PHARMACEUTICAL FORM

Eye ointment.

4. CLINICAL PARTICULARS

4.1 Suggested Use

HYLO NIGHT® is an eye ointment that improves the tear film and protects the surface of the eye.

4.2 Posology and method of administration

4.2.1 Dosage

Suitable for use in adults and children.

The frequency of application depends on the individual complaints and habits. In case of distinct sensation of dry eyes HYLO NIGHT® is usually used three times daily. Usually the application before going to bed at night is particularly recommended.

Leave an interval of at least 15 minutes before instilling another ophthalmic medication. Eye ointments should be applied at last.

4.2.2 Administration

For ocular use only.

4.3 Contraindications

Hypersensitivity to any of the excipients. HYLO NIGHT® should not be applied while wearing contact lenses.

4.4 Special warnings and precautions for use

Stop treatment and consult a physician if irritation persists or worsens or new eye signs or symptoms develop.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

HYLO NIGHT® can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

HYLO NIGHT® may cause blurring of vision because of the greasy consistency of the eye ointment. You should not drive a car, take actively part in traffic, use machines or work without secure hold during this time.

4.8 Undesirable effects

Transient blurred vision or a slight stinging sensation on instilling HYLO NIGHT®.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACEUTICAL PARTICULARS

5.1 List of excipients

Composition: Retinol

palmitate White

Vaseline Light liquid

paraffin Liquid paraffin

Wool fat

5.2 Incompatibilities

Not applicable.

5.3 Shelf life

3 years.

Discard any remaining eye ointment within 6 months of first use of the tube.

5.4 Special precautions for storage

Do not store above 25°C.

5.5 Nature and contents of container

Aluminium tube with 5 g of eye ointment.

5.6 Instructions for use and handling

Eye ointments should generally be used without contact of the tube with eye or skin.

Remove the protective cap, tilt your head backwards and gently pull on the lower eyelid using a finger of one hand. With the other hand hold the tube in an upright position above the eye. Instil a small strip (ca. 1 cm) of eye ointment into the gap formed between the eye and eyelid by gently squeezing on the tube. Close your eye gently, then blink normally. Replace the cap firmly back onto the tube. To avoid contamination, do not allow the tip of the tube to touch the eye or any other surface.

6. MANUFACTURER

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7. DISTRIBUTOR

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7. DATE OF REVISION OF THE TEXT

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