

SUMMARY OF PRODUCT INFORMATION

1. NAME OF THE MEDICAL DEVICE

HYDRAMED NIGHT, Eye ointment.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Retinol palmitate 250 IU/g.

Chamomile (matricaria chamomilla, liposoluble extract) 0.002%

Calendula (calendula officinalis, liposoluble extract) 0.002%

For the full list of excipients, see 5.1

3. PRODUCT FORM

Eye ointment. Smooth, homogeneous, yellowish-white, preservative-free ointment in a reclosable tube of 5g.

4. PRODUCT PARTICULARS

4.1 Suggested Use

HYDRAMED NIGHT is an eye ointment that improves the tear film and protects the surface of the eye, used in cases of moderate to severe dry eye and for overnight use.

4.2 Posology and method of administration

4.2.1 Dosage

Unless otherwise directed, instill a 10mm strip of the product onto the lower eyelid.

4.2.2 Administration

For topical ocular administration.

Suitable for use in adults, the elderly, and children.

4.3 Contraindications

Do not use if you are sensitive to any of the components.

4.4 Special warnings and precautions for use

To avoid contamination or possible eye injury, do not touch the tip to any surface and avoid contact with the eye or eye lashes.

Wash hands before administration of product.

Do not wear contact lenses during the instillation of the product. There should be an interval of at least 30 minutes before reinsertion.

In case of concomitant use of HYDRAMED NIGHT and other ophthalmic products, there should be an interval of at least 30 minutes between application of products and HYDRAMED NIGHT should be the last product instilled.

Stop use and consult a physician if irritation, pain, redness, or changes in vision occur persists or worsens or new eye signs or symptoms develop.

4.5 Interaction with medicinal products and other forms of interaction

No interactions have been observed.

4.6 Fertility, pregnancy, and lactation

There are no known fertility implications with the use of HYDRAMED NIGHT. No effects during pregnancy and on the breastfed infant are anticipated. Can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

The product has a long duration of action, blurring of vision may be substantial. Do not drive or use machinery unless vision is completely clear.

4.8 Undesirable effects

Blurred vision or a slight stinging sensation on instilling. Hypersensitivity to any of the ingredients.

4.9 Overdose

No case of overdose has been reported.

5. PRODUCT PARTICULARS

GMDN Classification: Code 44237 – lubricant eye drops

5.1 List of excipients

Wool fat (Lanolin)

Liquid paraffin (Vaseline oil)

White soft paraffin (White Vaseline/petroleum jelly)

5.2 Incompatibilities

Not applicable.

5.3 Shelf life

2 years. Once opened, the container can be used for up to 90 days.

Do not use if the container is damaged or after the expiry date shown

5.4 Special precautions for storage

Store between 15°C – 25°C.

6. MANUFACTURER AND COMPANY CONTACT DETAILS

UK Office: Farmigea Ophthalmics Limited, Suite 207, Oakland House, 21 Hope Carr Road, Leigh WN7 3ET Telephone: +44 (0)1942 367516. E-mail: info@farmigea.co.uk
www.farmigea.co.uk

Manufacturing site: Farmigea S.p.A – Via G.B. Oliva 6/8 – 56121 Pisa, Italy

7. DATE OF REVISION OF THE TEXT

April 2023