SUMMARY OF PRODUCT INFORMATION

1. NAME OF THE MEDICAL DEVICE
HYDRAMED FORTE 0.4% sodium hyaluronate w/v, TS-polysaccharide 0.2%, eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
1 ml contains 4 mg sodium hyaluronate and 2 mg TS-polysaccharide
For the full list of excipients, see 5.1.

3. PRODUCT FORM
Eye drops, solution in 0.5mg daily-dose reclosable vial and preservative-free, multidose 10ml bottle. Sterile clear solution.

4. PRODUCT PARTICULARS
4.1 Suggested Use
Tear substitute. A long lasting and soothing lubricant in the management of dehydration of the cornea and conjunctiva due to impaired lacrimal secretion and functional disorders as a result of topical or systemic diseases. Can be used on a damaged or compromised cornea, for instance, after ocular surgery, in contact lens use, conjunctivitis.

4.2 Posology and method of administration
4.2.1 Dosage
Unless otherwise directed, instill 1 drop into the conjunctival sac one or more times daily, to provide sufficient lubrication. Therapy of dry eye syndrome requires an individual dosage regimen.
4.2.2 Administration
For external ocular use only. Suitable for use in adults and children.
To avoid contamination or possible eye injury, do not touch the tip of the bottle or vial to any surface and avoid contact with the eye.
The eye drops may be used with contact lenses and/or ocular prosthesis.
Leave an interval of at least 15 minutes before instilling other eye drops.

4.3 Contraindications
Hypersensitivity to the active substance hyaluronic acid or to any of the excipients.

4.4 Special warnings and precautions for use
Stop use and consult a physician if irritation, pain, redness, or changes in vision occur, persist, or worsen or new eye signs or symptoms develop.

4.5 Interaction with medicinal products and other forms of interaction
None known.
For the use of concomitant ocular products, see section 4.2

4.6 Fertility, pregnancy, and lactation
There are no known fertility implications with the use of HYDRAMED FORTE. 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
On instillation may cause transient blurring of vision when first used. If affected wait until vision is completely clear before driving or operating machinery.

4.8 Undesirable effects
Brief 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
CND Classification: Q0299 – Ophthalmic devices - other
5.1 List of excipients:
Mannitol, sodium citrate, citric acid monohydrate, water for injection

5.2 Incompatibilities
Not applicable.

5.3 Shelf life
Reclosable vial: 3 years. Once opened, each vial can be used for up to 12 hours.
Preservative-free, multidose bottle: 3 years. Once opened, the bottle 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 below 25ºC

6. MANUFACTURER AND 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

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

7. DATE OF REVISION OF THE TEXT
April 2023