SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MAXMOIST (Sodium Hyaluronate and Dexpanthenol Ophthalmic Solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10ml bottle contains:
Sodium Hyaluronate BP .....1 mg
Dexpanthenol USP ..... 50 mg
Stabilized Oxychloro Complex..... 0.1 mg
(As Preservative)
Water for Injection USP q.s.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops

Clear, colourless solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For moisturizing the cornea and symptomatic treatment of dry eyes ("dry eye" syndrome); To stimulate reepithelialization in superficial lesions of the cornea.

4.2 Posology and method of administration

Posology

Suitable for long-term use.
Instill 1 or 2 drops in the affected eye(s) 2 – 5 times a day.

Method of administration

Topical route.
By Occular Instillation

4.3 Contraindications

Known or suspected hypersensitivity to any of the ingredients in the formula or to other hyaluronate acid-containing medications.

4.4 Special warnings and precautions for use

For topical ophthalmic use only Even when administered as indicated, this product may cause a transient blurring in vision. Do not use Maxmoist whilst using contact lens.

4.5 Interaction with other medicinal products and other forms of interaction

If other eye drops or eye ointments are being used concomitantly, an interval of 15 minutes should be observed between administrations of the different medicaments

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Maxmoist should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Maxmoist is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Maxmoist in pediatric patients have not been established.

4.7 Effects on ability to drive and use machines

Patients should exercise caution when driving vehicles or operating machines.

4.8Undesirable effects

Most common reported adverse reactions are:

- Blurred vision

- Eye redness or discomfort or other irritation not present before use of this medicine
- Increased sensitivity of eyes to light
- Matting or stickiness of eyelashes
- Swelling of eyelids
- Watering of eye

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse reactions via the pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS): https://pv.pharmacyboardkenya.org

4.9 Overdose

There is limited experience of overdose with Maxmoist. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacodynamic effects

Maxmoist contains sodium hyaluronate and dexpanthenol that perfectly moisturize the eye and soothe the irritation of various origins

Hyaluronic acid (in the form of sodium salt), which is part of the solution, is a natural polysaccharide compound contained in the tissues of the eye, as well as in other tissues and fluids of the human body.

Sodium hyaluronate molecules have a pronounced ability to bind water molecules. An aqueous solution of sodium hyaluronate has the necessary viscosity and high adhesive properties with respect to the cornea, thereby forming a uniform, persistent tear film on the cornea surface, which is not washed off during blinking and does not reduce visual acuity. Thus, the eye remains permanently protected from the sensation of dryness and irritation, which often occur on contact with the environment, as well as on wearing contact lenses.

Sodium hyaluronate also promotes corneal epithelial wound healing by rapid migration of cells leading to rapid wound closure. This may be facilitated by the adhesion between
CD44 on the cells and hyaluronic acid, which coats the surface of the denuded cornea

Dexapanthenol, which is a part of the solution, effectively supports the moisturizing properties of sodium hyaluronate and thus ensures the needs of eye tissue for intensive regeneration. It is necessary in the processes of reconstruction of epithelium, has regenerative and anti- inflammatory properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

MAXMOIST (Sodium Hyaluronate and Dexpanthenol Ophthalmic Solution)
Dexpanthenol

Sodium Hyaluronate

Oxychloro complex Sodium Citrate

Sodium Chloride

Citric Acid Monohydrate

Water for Injections

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 30 °C. Protect from light. Use within 2 weeks after opening.

6.5 Nature and contents of container

10 mL aqueous solution in 10 mL Teal green colour bottle. Such bottle packed in a carton along with the pack insert.

6.6 Special precautions for disposal and other handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

Ajanta Pharma Limited

Ajanta House, Charkop, Kandivli (West),

Mumbai- 400 067,

India

Manufacturing Site Address:

Ajanta Pharma Limited

Factory : Mirza-Palashbari Road,

Village Kokjhar,

Kamrup (R), Guwahati, Assam - 781128.

8. MARKETING AUTHORISATION NUMBER(S)

H2026/CTD11049/24157

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 March 2026

10. DATE OF REVISION OF THE TEXT

19-08-2026