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SUMMARY OF PRODUCT CHARACTERISTIC

1. Name of the medicinal product

VISCROSS

Sodium Hyaluronate 1.8 mg/mL.

Eye drops, solution

2. Qualitative and quantitative composition

Each 1 mL of solution contain Sodium Hyaluronate 1.8 mg

3. Pharmaceutical Form

Eye drops, solution

Clear and colorless sterile solution

4. Clinical Particulars

4.1 Therapeutic indications

Viscross (sodium hyaluronate ophthalmic solution), 0.18% are indicated for the treatment of dry eye and ocular surface damage due to some conditions and/or diseases for example, post operative eye surgeries; eg. cataract surgery, LASIK, prolonged use of preservative-containing eye drops such as antiglaucoma drugs. In addition, it can be used for the treatment of superficial keratitis, SjÖgren syndrome or primary dry eye syndrome (Keratoconjunctivitis sicca). Temporary relief of dryness, burning and ocular fatigue induced, for example, by dust smoke, dry heat, air conditioning, extended computer screen use or contact lens wear.

4.2 Posology and method of administration

Twist off cap. If not otherwise recommended, place one or two drops of Viscross into conjunctival sac of the eye as often as needed. Do not touch the tip of container to the eyes and/or any surface. After blinking, the solution will disperse and form a transparent and long- lasting coating on the surface of the eye. Viscross may also be used while wearing contact lenses (rigid or soft).

Special populations

Pediatric use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

4.3 Contraindication

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.
- Concomitant treatment with eye drops.
- Do not touch the tip of the opened container and do not touch the surface of the eye with the tip of the container.
- As Viscross does not contain preservatives it should be used and discarded after opening.
- Do not use Viscross if the container is damaged
- If discomfort persists while using Viscross or reappears after discontinuation of treatment, consult a physician.
- There is no experience regarding the safety of Viscross in human pregnancy or lactation. Administration during pregnancy or lactation is therefore depending on physician judgment.

4.5 Interaction with other medicinal products and other forms of interaction

Do not use Viscross at the same time as any other drug or product applied to the eye since it may modify their effects. If more than one type of eye drops are applied to the eye, administer them at least five minutes apart. Avoid using Viscross with quaternary ammonium compound.

4.6 Pregnancy and lactation

Pregnancy

Pregnancy Category B. Reproduction studies have been performed in rats and rabbits at doses of 50 mg/kg and have revealed no evidence of impaired fertility or harm to the fetus due to administration of sodium hyaluronate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should only be used during pregnancy if clearly needed.

Lactation

Caution should be exercised when Viscross is administered to a nursing women.

4.7 Effects on ability to drive and use machines

Patients who experience blurred vision after application of the eye drops should not drive or use machinery until their vision has cleared.

4.8 Undesirable effects

Dry eye, eye pain, eye irritation, foreign-body sensation, eye pruritus, visual acuity reduced, vision blurred, ocular hyperemia, eyelid margin crusting

4.9 Overdose

Given the nature of the product and the route of administration, no problems of overdosage are expected as the excess fluid will flow from the eye. A toxicology study following topical ocular administration of sodium hyaluronate, conducted in the rabbit, showed that overdosing with sodium hyaluronate did not result in any clinical or histological adverse events.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

ATC code: S01XA20 – artificial tears and other indifferent preparations; Belongs to the class of other ophthalmologicals.

Sodium hyaluronate is a polysaccharide (glycosaminoglycan) consisting of a sequence of disaccharide units, linked to each other by a β1 -->3 bond. This disaccharide unit repeats itself, forming a linear chain of high molecular weight which, in physiological saline solution, assumes a random coil configuration characterized by a large hydration volume. The sodium hyaluronate used in Viscross is obtained by bacterial fermentation and purification and is comprised of a specific fraction with a high degree of purity. The most important property of sodium hyaluronate is its viscoelasticity. This physicochemical property mechanistically leads to the following actions after topical instillation to the eye:

1) During blinking, shear stress causes the sodium hyaluronate molecules in solution to align with one another; as a result, the solution becomes elastic and relatively nonviscous, and spreads easily over the surface of the cornea.

2) Between blinks, the molecules of sodium hyaluronate form a tangled meshwork, and the solution becomes less elastic and more viscous; consequently, the precorneal tear film is stabilized and the residence time of the solution on the surface is maximized. Due to the coiled structure of the sodium hyaluronate molecule, Viscross is highly effective in entrapping water. With effective water entrapment, the rate of tear evaporation is slowed. Sodium hyaluronate solutions adhere to the mucin layer of the precorneal tear film. These physicochemical properties of the molecule, together with observed pharmacodynamics effects, such as increased corneal wound healing, ameliorate the signs and symptoms typically associated with dry eye disease. Sodium hyaluronate promotes migration of human corneal epithelial cells in vitro, leading to beneficial effects on corneal wound healing.

5.2 Pharmacokinetic properties

Due to its high molecular weight, sodium hyaluronate is not expected to pass through the conjunctiva and the corneal epithelium. Following intraocular administration of sodium hyaluronate, the t½ for elimination of the product from the aqueous humor was around 10.5 hours and no product was detected 24 hours after administration. After parenteral administration of sodium hyaluronate, this molecule is efficiently metabolized in the liver (t½=2.5 to 5.5 minutes).

5.3 Preclinical safety data

No maternal toxicity, fetal toxicity, or teratogenic effects on the fetuses of treated dams (rats or rabbits) has been observed after subcutaneous sodium hyaluronate administration at doses up to 50 mg/kg/day. Sodium hyaluronate has shown no mutagenic or clastogenic potential in bacterial assays and cytogenetic assays conducted both in vitro and in vivo. No toxic effects following acute and subacute topical ocular administration in albino rabbits and rabbits with pigmented eyes; no acute toxic effects following injection into the anterior chamber or vitreous body of monkey eyes; and no acute toxic effects in mice or rats following oral, intraperitoneal, or subcutaneous administration. Chronic administration studies of sodium hyaluronate in rats or dogs following

subcutaneous administration showed no toxic effects, with the exception of local tissue hardening and/or edema at the injection site which was reversible. No antigenicity was detected in guinea pigs, mice, or rabbits after parenteral administration.

6. Pharmaceutical Particulars

6.1 List of excipients

- Sodium chloride
- Potassium chloride
- Calcium chloride
- Magnesium chloride
- Sodium citrate
- Dibasic sodium phosphate
- Water for injection
- Hydrochloric acid

6.2 Incompatibilities

Quaternary ammonium compound

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

VISCROSS is contain in clear plastic ampoule (LDPE) of 0.3 mL in the paper box of 10, 20, 30, 50, 60 and 100 ampoules

7. Manufacturer

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8. Marketing authorisation number(s)

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9. Date of first authorisation/ renewal of the authorisation

xx.xx.xx

10. Date of revision of the text

31 March 2022