For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

SenHylo™

Eye Drops 5 mL

(Sodium Hyaluronate Eye Drops 0.1% w/v)

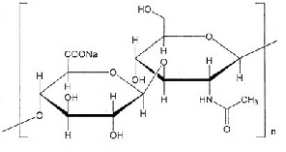
COMPOSITION:

Sodium Hyaluronate BP ..... 0.1% w/v
Stabilized Oxychloro Complex (as preservative) ..... 0.005% w/v
Water for Injections IP ..... q.s.

Inactive Ingredients: Sodium Chloride, Boric Acid, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride, Sodium Hydroxide (for pH adjustment) in Water for Injection.

Dry eye patients present with instability of the pre-corneal tear film which breaks up much earlier than normal. The instability of the pre-corneal tear film leads to dry eye symptoms such as the sensation of sand in the eye, recurrent blurred vision, itching and the sensation of dryness.

Chemical Structure of Sodium Hyaluronate



Pharmacological Action:

The main objective of dry eye treatment is to increase the pre-corneal tear film stability. SenHylo as a tear substitute behaves like a pseudo plastic fluid. This indicates that at very low shear the solution has a very high viscosity and relatively low elasticity, and at higher shear the solution is extremely elastic. These Viscoelastic properties are important to lubricate. In addition, the water binding capacity of SenHylo keeps the eye's surface wet. SenHylo solution forms a lubricating moisture film on the surface of the eye that is not easily rinsed off. The macromolecule Sodium Hyaluronate has bio adhesiveness mucomimetic properties when applied to the eye because of interactions with the pre- corneal mucin layer. By this, the solution spreads out very well and forms a regular, stable and long-lasting tear film. It however does not cause blurred vision and protects the eyes from dryness and irritation for a long time. In SenHylo Eye Drops Sodium Hyaluronate acts in a physico-chernial manner without pharmacological action by lubricating the ocular surface.

SenHylo Eye Drops binds to many extracellular matrix molecules specifically to cell bodies through cell surface receptors like CD44. Expression of CD44 is increased in patients with moderate dry eye and superficial keratitis. SenHylo Eye Drops might have a direct role in control of ocular surface inflammation in dry eye patients because it is associated with a decreased expression of CD44 in patients with moderate eye and superficial keratitis.

The duration of contact with the ocular surface (the so-called residence time) is important for the efficacy of artificial tears.

Contra-indications: SenHylo is contraindicated in patients hypersensitivity to any of the ingredients.

Warnings and Precautions:

- If irritation pain, redness or changes in vision occur or if the patients condition worsens, treatment discontinuation should be considered.

Pregnancy and Lactation:

SenHylo eye drops can be applied during pregnancy and lactation as there is no side effect.

Dosage and Directions For Use:

Instill 1 to 2 drops in the affected eye(s) as needed or as directed by Physician.

Rewetting indication:

To lubricate and rewet soft and rigid gas-permeable lenses during the day: With the lenses on the eye, apply 1 to 2 drops to each eye as needed, or as directed by the eye care practitioner. Blink several times.

Storage and handling instructions:

Store below 30°C, Do not freeze, Protect from light

Use the solution within one month after opening the container.

Do not touch the tip of the container to any surface. Replace cap after using.

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

Presentation: SenHylo is supplied in an opaque LDPE dropper bottle with a containing 5 mL of clear colourless solution.

Directions for use:

Turn the tamper proof cap anti clockwise to break the seal and remove the cap.

Remove and discard the tamper proof ring from the container.

Tilt your head back. Gently pull your lower eyelid downwards to form a pocket between your eyelid and your eye, look up.

Turn the container upside down, place the dropper tip close to your eye but be careful not to touch your eye with it and gently press the container with thumb and index finger to dispense the drop.

Replace the cap by turning clockwise direction until it is firmly touching the bottle. Do not overtighten the cap.

Manufactured in INDIA by :

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