

Cellwet[®] Ultra Hydrate

Eye Drops

Sodium Hyaluronate, Polyethylene Glycol 400
& Propylene Glycol Lubricant Eye Drops

COMPOSITION:

Sodium Hyaluronate BP	0.15% w/v
Polyethylene Glycol 400 IP	0.4% w/v
Propylene Glycol IP	0.3% w/v
Stabilized Oxychloro Complex	0.005% w/v
(as preservative)	
Water for Injection IP	q.s.

Sodium Hyaluronate (0.15%w/v), Polyethylene Glycol 400 (0.4%w/v) and Propylene Glycol (0.3%w/v) Lubricant Eye Drops:

Cellwet Ultra Hydrate belongs to the class of 'ophthalmic lubricants' that treat dry eyes. A dry eye is a disorder of the tear film of the eye that leads to the deficiency of tears or extreme evaporation of the tears causing damage to the ocular surface.

Cellwet Ultra Hydrate is a combination of Sodium Hyaluronate, Polyethylene Glycol, and Propylene Glycol. Sodium Hyaluronate, a natural polysaccharide found abundantly in the extracellular matrix of connective tissues, plays a crucial role in maintaining ocular hydration and lubrication. It helps relieve burning sensations, dryness, and discomfort. Polyethylene glycol 400, a water-soluble polymer with lubricating properties, enhances the retention of moisture on the ocular surface. Propylene glycol, a humectant and solvent, further aids in preserving hydration and facilitating drug delivery.

Mechanism of Action:

The synergistic action of sodium hyaluronate, PEG 400, and propylene glycol addresses the multifactorial nature of dry eye syndrome and related ocular surface disorders. Sodium hyaluronate forms a viscoelastic film over the cornea and conjunctiva, providing prolonged lubrication and protection against environmental irritants. PEG 400 acts as a wetting agent, spreading evenly across the ocular surface to maintain hydration and reduce friction during blinking. Propylene glycol enhances the solubility and bioavailability of active ingredients while preventing evaporation of the tear film, thereby promoting long-lasting relief and comfort.

Benefits:

1. Enhanced Lubrication:

Sodium hyaluronate forms a stable and lubricating film, reducing friction and discomfort associated with dry eyes.

2. Prolonged Moisture Retention:

PEG 400 and propylene glycol maintain hydration on the ocular surface, alleviating symptoms of dryness and irritation.

3. Improved Drug Delivery:

Propylene glycol enhances the solubility and bioavailability of therapeutic agents, ensuring effective treatment of underlying ocular conditions.

4. Long-lasting Relief:

The combined action of these ingredients provides sustained relief from dry eye symptoms, promoting ocular comfort and well-being.

Applications:

1. Dry Eye Syndrome:

These formulations offer symptomatic relief by replenishing and stabilizing the tear film, improving ocular lubrication, and reducing ocular surface inflammation.

2. Ocular Surface Disorders:

Sodium hyaluronate, PEG 400, and propylene glycol address epithelial damage, keratitis, and other corneal abnormalities associated with ocular surface diseases.

3. Contact Lens Discomfort:

These eye drops alleviate discomfort and dryness induced by contact lens wear, enhancing lens tolerance and comfort throughout the day.

4. Pre- and Post-Operative Care:

They are employed in pre-operative preparation and post-operative management of patients undergoing ocular surgeries, facilitating tissue healing and minimizing post-operative complications.

Clinical Particulars

Therapeutic Indications

For the temporary relief of burning and irritation due to dryness of the eye and for use in lubricating

Posology and Method of Administration

Posology

Pediatric Population

The safety and efficacy of Sodium Hyaluronate, Polyethylene Glycol 400 and Propylene Glycol Eye Drops in children has not been established.

Contraindications

People allergic to any ingredient in Sodium Hyaluronate, Polyethylene Glycol 400 and Propylene Glycol Eye Drops should not use these products.

Drug Interactions

No clinically relevant interactions have been described.

Use in Special Population

Pregnant Women

There are no adequate data regarding the use in pregnant women. All of the ingredients in this product are pharmacologically inert compounds, generally classified as non-toxic and non-irritating, therefore no effect during pregnancy is anticipated. This product can be used during pregnancy.

Lactating Women

There are no adequate data regarding the impact of Sodium Hyaluronate, Polyethylene Glycol 400 and Propylene Glycol Eye Drops on lactation. All of the ingredients in this product are pharmacologically inert compounds, generally classified as non-toxic and non-irritating, therefore no effect during lactation is anticipated. This product can be used during breastfeeding.

Pediatric Patients

The safety and efficacy of Sodium Hyaluronate, Polyethylene Glycol 400 and Propylene Glycol Eye Drops in children has not been established.

Fertility

There are no adequate data regarding the impact of Sodium Hyaluronate, Polyethylene Glycol 400 and Propylene Glycol Eye Drops on fertility. All of the ingredients in this product are pharmacologically inert compounds, generally classified as non-toxic and non-irritating.

Effects on ability to drive and use machines

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machines.

Overdose

Due to the characteristics of this preparation, no toxic effect is to be expected with an ocular overdose of this product, nor in the event of an accidental ingestion of the contents of one bottle.

Storage

Store Below 30°C, Protect from light. Do Not Freeze

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

Solution to be used within one month after opening the container.

Presentation

Cellwet Ultra Hydrate is a clear slightly viscous & sterile solution supplied in plastic opaque dropper bottle with a cap, containing 10mL of the 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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