Summary of Product Characteristics
(Product Data Sheet)

Product Name: SOFTDROPS
(Carboxymethylcellulose Sodium 0.5% w/v and Glycerin 0.5% w/v Eye Drops)

Qualitative & Quantitative Composition:

Carboxymethylcellulose Sodium USP	0.5% w/v
Glycerin BP	0.5% w/v
Stabilized Oxychloro Complex (As Preservative)	0.01% w/v
Sterile aqueous vehicle	q.s

Pharmaceutical Form:

Eye Drops
Colourless to pale yellow colour clear solution, free from visible particles.

Clinical Particulars

Therapeutic Indications:
For the temporary relief of burning, irritation and discomfort due to dryness of the eye or from irritation from wind or sun.
May be used to protect against further irritation

Posology and Method of administration:

Method of Administration

Instill 1 or 2 drops of Softdrops in the affected eye (s) as needed.

If Softdrops is used to lubricate and rewet contact lenses, apply 1 or 2 drops to each eye as needed with the contact lens on the eye. If desired, 1 or 2 drops of Softdrops may be placed on the contact lens before insertion.
It is recommended for the patients to follow their ophthalmologist's instructions.

Pediatric Use
Safety and effectiveness have not been demonstrated in pediatric patients

Geriatric Use
No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

Contraindications:

Softdrops is contraindicated in patients with hypersensitivity to active ingredients or to any of the excipients listed.

Special warning and precautions for use:

To avoid contamination or possible eye injury, do not touch tip of the bottle or vial to any surface and avoid contact with the eye. Re-cap after use. Do not use if Softdrops packaging shows evidence of tampering. Do not use if solution changes colour or becomes cloudy. Discontinue use of Softdrops and consult a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens. Use before the expiration date marked on the container.

Allow 5 minutes between the administrations of ophthalmic products.

Interactions with other medicinal products and other forms of Interactions :

No interactions are anticipated in humans, since systemic concentrations of Glycerin and Sodium carboxymethylcellulose are extremely low for ocular dosing.

Pregnancy and Lactation:

Pregnancy
There are no specific study data on the use of Softdrops during pregnancy and lactation in humans; however, animal studies with CMC have not demonstrated any harmful effects in pregnancy. Animal studies using glycerine have shown no evidence of teratogenicity.

Lactation
Softdrops has also not been studied in breast-feeding women; however, Softdrops is not expected to have significant systemic absorption; therefore, it would not be excreted in human breast milk.

Effects on ability to drive and use machine

Softdrops may cause transient blurring of vision which may impair the ability to drive or operate machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machinery.

Adverse effects:

The common adverse effects are conjunctival/ ocular hyperemia, Dry eye, eye pain, eye pruritus, erythema of eyelid, blurred vision.
Other adverse effects which may occur are eye discharge, eye irritation, eyelid edema, foreign body sensation in eyes, lacrimation increased, eye swelling and hypersensitivity.

Overdosage:

Since carboxymethylcellulose sodium is pharmacologically inert and not absorbed systemically, systemic intoxication from topical overdose is not expected from ocular administration of Softdrops. Additionally, no adverse effects are expected should accidental systemic overdose occur.

Glycerine is a small molecule that is found throughout the body as a natural metabolic compound. In the low concentrations present in Softdrops, it will combine with endogenous glycerine in the body tissues without significant effect. Systemic intoxication from topical overdose is not expected given the low systemic exposure of glycerine via topical administration of Softdrops.

Pharmacological properties

Pharmacodynamic Properties:

Softdrops is a lubricating formulation similar to normal tears.

Carboxymethylcellulose sodium has no pharmacological receptor-mediated properties. The mode of action of carboxymethylcellulose sodium is based on its physical properties which provide a lubricant effect and prolonged residence time in the eye. Carboxymethylcellulose sodium increases tear viscosity and has pseudo-elastic (i.e. shear thinning) properties. Since carboxymethylcel1ulose sodium is an ionic polymer containing carboxyl and hydroxyl groups, its chemical structure is similar to mucin in the tear film, and thus it has mucoadhesive properties. These properties promote prolonged residence times in the eye which alleviate the symptoms of tear deficiency.

Pharmacokinetics Properties:

Carboxymethylcellulose sodium is pharmacologically inert and not absorbed systemically it is not expected that safety concerns win arise from the topical administration of Softdrops.

Glycerin is a 3 - carbon alcohol that is naturally occurring in the human body. Glycerine is rapidly absorbed in the intestine and the stomach, distributed over the extracellular space and excreted. It is metabolized to glucose and glycogen and may also combine with free fatty acids to form triglycerides which are distributed to adipose tissue where cell turnover occurs. Systemic intoxication from topical overdose is not expected given the low systemic exposure of glycerine via topical administration of Softdrops.

Preclinical Safety data:

Ocular Toxicology Studies
Rabbits were given topical ocular instillations of 2 drops of carboxymethylcellulose sodium and glycerine eye drop, 8 times daily (approximately at 1 hour intervals) for 28 consecutive days. Based on Jack of gross ocular irritation observations, ophthalmic examination observations (slit lamp biomicroscopy and ophthalmoscopy), intraocular pressure (lOP) changes, and macroscopic and microscopic pathology of ocular tissues. Carboxymethylcellulose sodium and glycerine eye drop was well tolerated. Rabbits were given topical ocular instillations of one drop of combination of carboxymethylcellulose sodium and glycerine eye drop 7 times daily for 23 consecutive days with or without contact lens wear. carboxymethylcellulose sodium and glycerine eye drop was well-tolerated when used with contact lenses based on gross ocular observations, ophthalmic examinations, and macroscopic and microscopic ocular pathology.

Carcinogenicity and Mutagenicity Studies
No evidence of carcinogenicity was observed in oral studies in rats and mice receiving doses of CMC ranging from approximately 1000 mg/l<g/day to 10,000 mg/kg/day. No mutagenic effects were observed with CMC in the Ames test with the without activation.

Fertility Studies
There were no effects on fertility in a multi-generational study in rats at doses up to 1000mg/kg/day of CMC. These doses in rats were approximately 16,000 times higher than the maximum expected clinical exposure of. 0.06 mg/kg/day (at 6 drops/eye/day in a 50 kg person), assuming that the entire dose is absorbed. Reproductive and developmental studies in rats given up to 1180 mg/kg glycerine did not show any adverse effects on reproductive parameters and there was no evidence of teratogenicity.

Pharmaceutical particulars

List of Excipients:
N-acetyl Carnosine IH,Synthetic Retinol Concentrate BP, All- Rac-Alpha-Tocopheryl Acetate BP, Polyoxyl 35 Castor Oil, Boric Acid BP, Sodium Perborate BP, Borax BP, Sodium Citrate BP,Potassium Chloride,BP, Magnesium Chloride Hexahydrate BP, Calcium Chloride Dihydrate BP, Sodium Chloride BP, Hydrochloric Acid BP, Sodium Hydroxide BP, Water for Injections BP.

Incompatibilities: Not applicable

Special Precautions for storage: Use the solution within one month after opening the vial.

Storage Condition: Store below 30ºC. Protect from light.

Nature and contents of container:
10 mL solution in LDPE vial packed in a carton along with the pack insert.

Marketing Authorization Holder:
Manufacturing Site :
Ajanta Pharma Ltd.
Mirza - Palashbhari Road,
Village Kokhjar, Kamrup (R),
Guwahati, Assam – 781128

Registered office:
Ajanta House,
Charkop, Kandiali (W),
Mumbai 400 067
India.

Date of revision of text

May, 2023