



MEDICAL DEVICE LIST

Protecting
Eyesight,
Preserving
Generations



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 106242 0002 Rev. 00

Manufacturer:

Kilitch Healthcare India Limited

R-904,905, T.T.C., Industrial Area, MIDC

Rabale

Navi Mumbai, Dist.-Thane, Maharashtra 400701

INDIA

Product Category(ies):

1. Sodium Hyaluronate Ophthalmic Solution (In Dropper Bottle).
2. Hydroxypropyl Methylcellulose Eye Drops (Hypromellose Eye Drops) In Dropper Bottle.
3. Carboxymethylcellulose Eye Drops (Carmellose Sodium Eye Drops) In Dropper Bottle.
4. Propylene Glycol Eye Drops (In Dropper Bottle).

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1_106242_0002_Rev_00

Report No.: IND20190104

Valid from: 2020-08-20

Valid until: 2024-05-26

Date, 2020-08-20

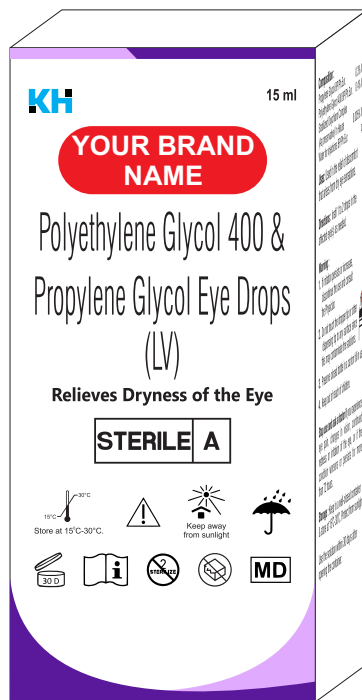
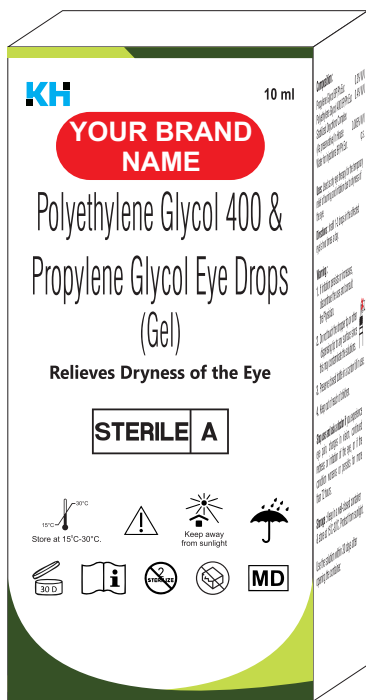
Christoph Dicks
Head of Certification/Notified Body

Help your eyes feel lubricated & refreshed

Propylene Glycol Eye Drops

To get relief against the sensation of Dryness, Discomfort & Irritation of eyes

- 💧 Polyethylene Glycol 400 & Propylene Glycol moisturize the eye & work similar to natural tears by counteracting dryness of eye.
- 💧 Propylene Glycol is lipid lubricating emulsion which lubricates ocular surface & stabilize lipid layer of tear film reduces excessive tear evaporation.



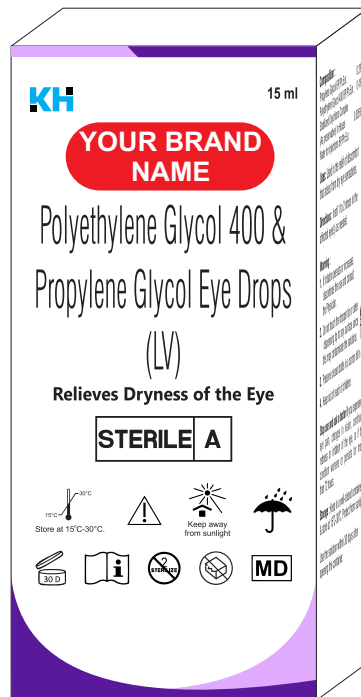
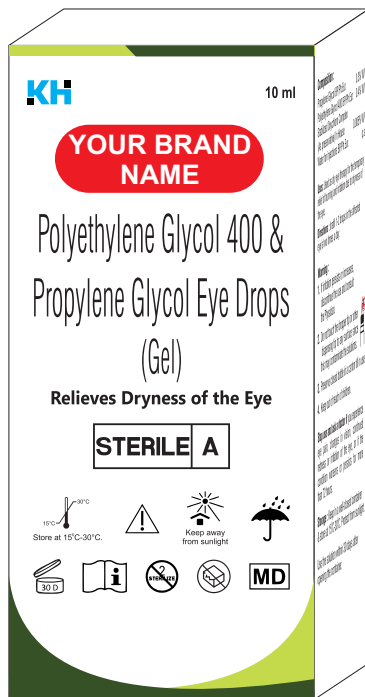
Propylene Glycol Eye Drops

Advantages:

- Lubricating Eye Drops help replace your eye's natural moisture when your eye's aren't making enough on their own.
- They relieve dryness & irritation, promoting comfort.

Indications:

- Propylene Glycol Eye Drops Device is a dry eye therapy for the temporary relief of burning and irritation due to dryness of the eye.



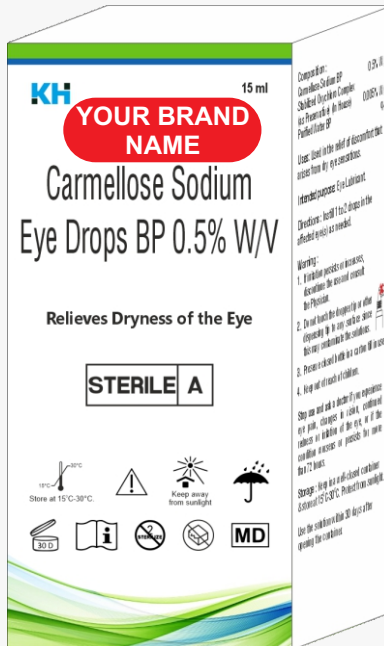
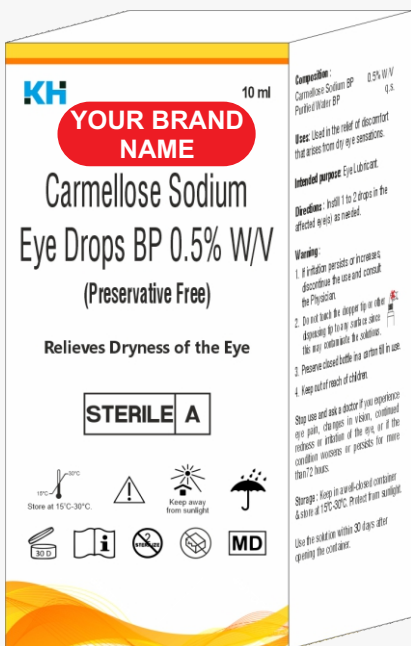
Description	Packing	Remark	Class
Polyethylene Glycol 400 & Propylene Glycol Eye Drops	10 ml LDPE Dropper Bottle	Gel	IIb
Polyethylene Glycol 400 & Propylene Glycol Eye Drops	15 ml LDPE Dropper Bottle	LV	IIb
Propylene Glycol Eye Drops 0.6% w/v	10 ml LDPE Dropper Bottle		IIb

Help your eyes feel lubricated & refreshed

Carmellose Sodium Eye Drops BP 0.5% & 1% W/V

To get relief against the sensation of Dryness, Discomfort & Irritation of eyes

- 💧 **Substitute for tears in relief of discomfort towards blurry vision and burning sensation.**
- 💧 **Improve corneal surface wettability and tearfilm integrity.**
- 💧 **Improve clinical symptoms in case of dry eye associated with TV & Computer screens, infrequent blinking, refractive laser eye surgery, atmospheric pollution and drying atmosphere.**



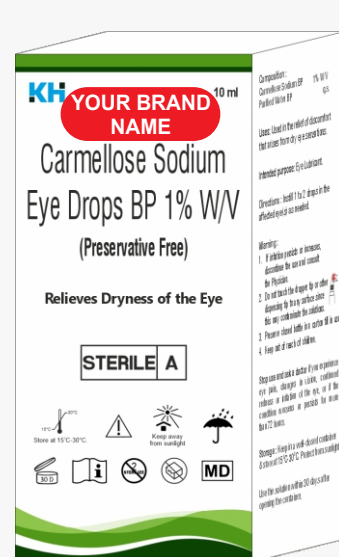
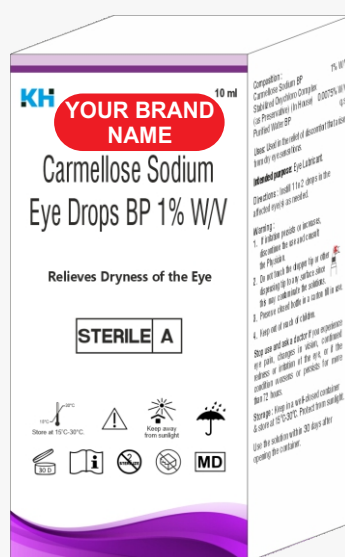
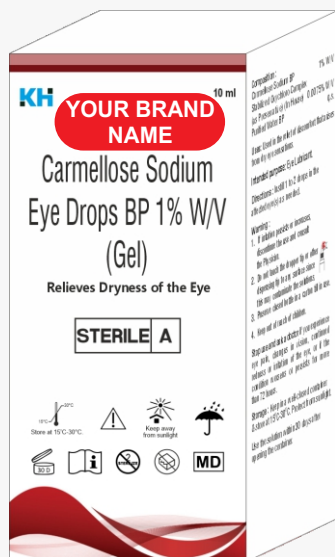
Carmellose Sodium Eye Drops BP 0.5% & 1% W/V

Advantages :

- Increases retention time and provides mucomimic, mucoadhesion on ocular surface.
- Stabilizes the tearfilm in case of dry irritated eyes.
- For long lasting relief of tired and watery eyes.

Indications :

- Relief of discomfort that arises from dry eye sensation.
- Provides soothing relief for sore eyes.
- Relief in case of further irritation from grit, itchinness and other foreign body irritations.



Description	Packing	Remark	Class
Carmellose Sodium Eye Drops BP 0.5% w/v	10 ml /15 ml Dropper Bottle		IIb
Carmellose Sodium Eye Drops BP 1% w/v	10 ml Dropper Bottle		IIb
Carmellose Sodium Eye Drops BP 0.5% w/v (Preservative Free)	10 ml Dropper Bottle		IIb
Carmellose Sodium Eye Drops BP 1% w/v (Preservative Free)	10 ml Dropper Bottle		IIb
Carmellose Sodium Eye Drops BP 1% w/v	10 ml /15 ml Dropper Bottle	Gel	IIb

For Moderate to Severe Dry Eyes

Sodium Hyaluronate Ophthalmic Solution

- ▼ Sodium Hyaluronate Ophthalmic Solution is highly pure form of hyaluronic acid¹
- ▼ Sodium Hyaluronate is manufactured by the unique method of bacillus fermentation¹
- ▼ Sodium Hyaluronate Ophthalmic solution used for treatment of dry eyes and burning sensations due to environmental conditions²



Purity is the key to clear vision

Sodium Hyaluronate Ophthalmic Solution



Advantages

- Decreases tear evaporation rate
- Increases pre-corneal tear film stability & corneal wettability

Indications

- Dry eye syndrome
- Burning sensations due to environmental conditions.
- Contact lens wearer
- Ocular surface damage due to diseases like superficial keratitis

Description	Packing	Class
Sodium Hyaluronate Ophthalmic Solution 0.3 % W/V (PF)	10 ml LDPE Dropper Bottle	IIb
Sodium Hyaluronate Ophthalmic Solution 0.18 % W/V (PF)	10 ml LDPE Dropper Bottle	IIb
Sodium Hyaluronate Ophthalmic Solution 0.1 % W/V	10 ml LDPE Dropper Bottle	IIb
Sodium Hyaluronate Ophthalmic Solution 0.18 % W/V	10 ml LDPE Dropper Bottle	IIb
Sodium Hyaluronate Ophthalmic Solution 0.1 % W/V (PF)	10 ml LDPE Dropper Bottle	IIb

5 Properties of Sodium Hyaluronate Ophthalmic Solution

Lubricant

Viscoelasticity

Mucomimesis

Mucoadhesive

Water retention & Wetting

Help your eyes feel lubricated & refreshed

Hydroxypropyl Methylcellulose Eye Drops

To get relief against the sensation of Dryness, Discomfort & Irritation of eyes

- 💧 **Substitute for tears in relief of discomfort towards blurry vision and burning sensation.**
- 💧 **Improve corneal surface wettability and tearfilm integrity.**
- 💧 **Improve clinical symptoms in case of dry eye associated with TV & Computer screens, infrequent blinking, refractive laser eye surgery, atmospheric pollution and drying atmosphere.**

Description	Packing	Remark	Class
Hypromellose 0.3 % W/V + Glycerol 0.2 % W/V + Dextran 70 - 0.1 % W/V Ophthalmic Solution	10 ml Dropper Bottle		IIb
Hypromellose 0.3 % W/V + Glycerol 0.2 % W/V + Dextran 70 - 0.1 % W/V Ophthalmic Solution (Preservative Free)	10 ml Dropper Bottle		IIb
Hypromellose Eye Drops BP 0.3 % W/V	10 ml /15 ml Dropper Bottle		IIb
Hypromellose Eye Drops BP 0.3 % W/V (Preservative Free)	10 ml Dropper Bottle		IIb

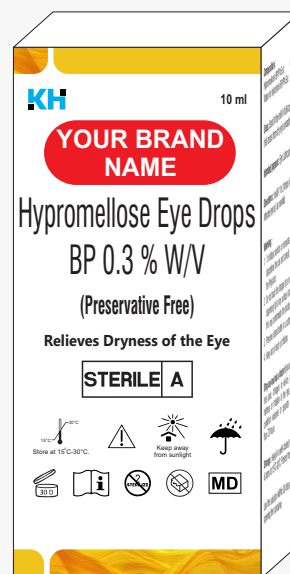
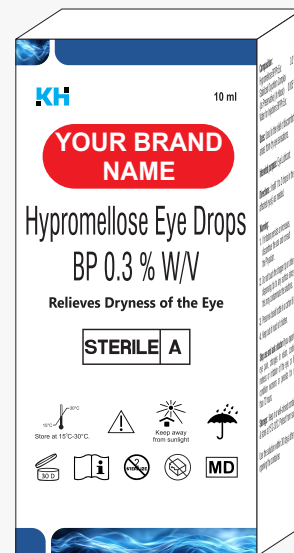
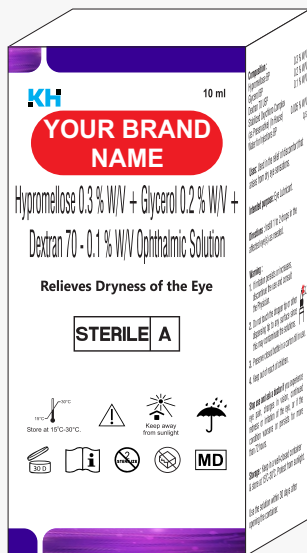
Hydroxypropyl Methylcellulose Eye Drops

Advantages :

- Increases retention time and provides mucomimic, mucoadhesion on ocular surface.
- Stabilizes the tearfilm in case of dry irritated eyes.
- For long lasting relief of tired and watery eyes.

Indications :

- Relief of discomfort that arises from dry eye sensation.
- Provides soothing relief for sore eyes.
- Relief in case of further irritation from grit, itchiness and other foreign body irritations.



Hypromellose Ophthalmic Solution USP 2% W/V (PFS)

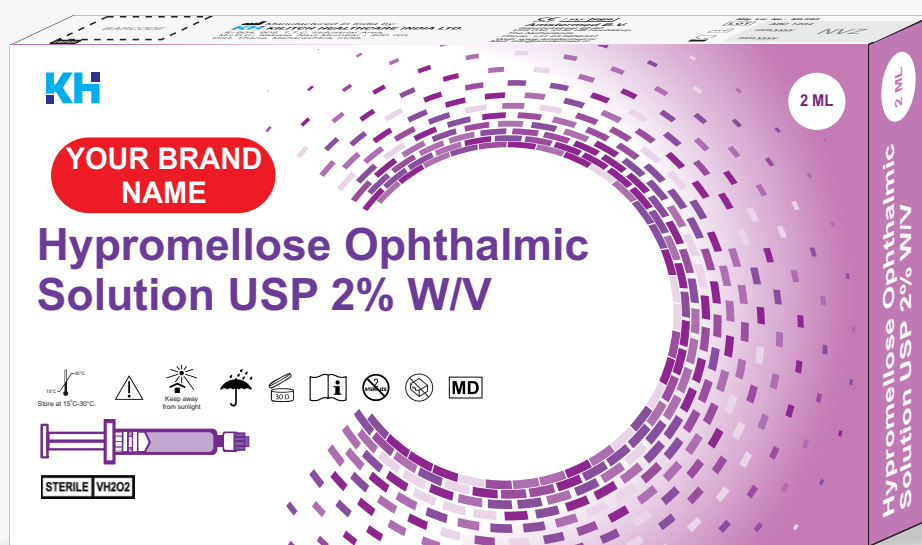
Hypromellose Ophthalmic Solution USP 2% W/V (PFS) is a sterile, isotonic, non-pyrogenic viscoelastic solution of highly purified, noninflammatory, 2% Hypromellose with a high molecular weight. Hypromellose Ophthalmic Solution USP 2% W/V (PFS) is supplied in 2 ml Pre-filled syringes. Each ml provides 20mg/ml of Hypromellose dissolved in a isotonic physiological balanced salt solution. It contains no preservative.

Properties :

1. Indicated as ophthalmic surgical aid in anterior segment surgical procedures.
2. Useful in intra-operative surgical procedures like cataract extraction and intraocular lens implantation, corneal and glaucoma surgery.
3. Maintains a deep chamber during anterior segment surgery.
4. Allows for more efficient manipulation with less trauma to the corneal endothelium and other ocular tissues.
5. Easily removable at the end of the surgery

Packaging :

1. Medical grade blister and sterile packaging.
2. Supplied with one sterile single use 23G cannula.





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The Pioneer in Manufacturing Sterile Dosage Forms