

SUMMARY OF PRODUCT CHARACTERISTICS**1 - Name of Medicinal Product:****1.1 Product Name:**

Brand Name: OPTOVISC Eye Drops

Generic Name : Hypromellose Ophthalmic Solution USP, 0.3%

1.2 Dosage Strength : 0.3%

1.3 Dosage Form : Ophthalmic Solution (Eye Drops)

2 - Qualitative & Quantitative Composition:

Each mL contains: Hypromellose USP 3 mg

3 - Pharmaceutical Form: Clear, colorless solution.**4 - Clinical Particulars****4.1 Therapeutic indications:**It is used as a soothing emollient solution in cases of tear deficiency.
Dry eye syndromes associated with deficient tear secretion.**4.2 Posology and method of administration:**Instill 1 to 2 drops into the eye(s) as often as needed to relieve the
dry and hot symptoms.**4.3 Contraindications:**This product contains Benzalkonium chloride and should not be
used when soft contact lenses are being worn.**4.4 Special warning and precautions for use**If the hot and dry symptoms persist, discontinue use and see a
doctor. Keep the surface of the dropper clean. Keep away from
children.**4.5 Interaction with other medicinal products and other forms of interactions:**

None known

4.6 Pregnancy and Lactation: None known**4.7 Effects of the ability to drive and use machines:** None known**4.8 Undesirable Effects:** No side effects has been published

4.9 Overdose and special antidotes: None known**5-Pharmacological Properties:****PHARMACOLOGICAL DATA
OF
OPTOVISC EYE DROPS**

Hydropropyl Methylcellulose or hypromellose in OPTOVISC prolongs the action of medicated eye drops and is employed in alkaline eye drops used as artificial tears to prevent damage to the cornea in patients with keratoconjunctivitis sicca or keratitis during gonioscopy procedures. Hypromellose is also used to moisten hard contact lenses and to lubricate artificial eyes.

Ref. Martindale 31st edition, p. 1539

PHARMACOKINETIC DATA

The effect of OPTOVISC is instant and simultaneous with the application. The frequency is dictated with the severity of the symptoms.

There is no data yet regarding the absorption of Hypromellose into the body through optical means.

6-Pharmaceutical Particulars :**6.1 List of excipients**

1. Sodium Borate NF
2. Boric Acid NF
3. Sodium Chloride USP
4. Potassium Chloride USP
5. Benzalkonium Chloride 50 % Solution NF
6. Purified Water USP

6.2 Incompatibilities : None**6.3 Shelf life :**

- (a) as packages for sale : **3 years**
- (b) After first opening: **Discard 4 weeks from opening**

6.4 Special precautions for storage:

Store at temperature 5°C – 30°C.

6.5 Nature and contents of container :

10 mL, packed in LDPE white bottle with HDPE white cap



7-Marketing Authorization Holder : **Linkabs Pharmaceuticals Ltd.**

8-Marketing Authorization Numbers : **04-9779**

9-Date of first authorization/renewal of the authorization : **25 June 2019**

10-Date of revision of the text : --