



SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product:

- 1.1 Product Name : **SALACYN 5% Eye Drops**
(Sodium Chloride Ophthalmic Solution USP, 5%)
- 1.2 Strength: **5%**
- 1.3 Pharmaceutical Dosage Form: **Ophthalmic Solution (Eye Drops)**

2-Quality and Quantitative Composition:

Each mL contains: : **Sodium Chloride 50 mg**

3-Pharmaceutical Form: Ophthalmic solution (Eye Drops)

4-Clinical Particulars

4.1 Therapeutic indications:

Salacyn 5% Eye Drops is used for the temporary relief of corneal edema.

4.2 Posology and method of administration:

Instill one to two drops in the affected eye(s) every 3 to 4 hours, or as directed by the doctor.

4.3 Contraindications:

No contraindications have been reported so far.

4.4 Special warning and precautions for use:

Salacyn 5% Eye Drops should not be used with soft contact lenses. Do not allow dropper nozzle to touch the eyelid.

4.5 Interaction with other medicinal products and other forms of interactions:

No drug interaction or incompatibility has been reported so far.

4.6 Pregnancy and Lactation There are no adequate and well controlled studies in pregnant women:

None known

4.7 Effects of the ability to drive and use machines:

None known

4.8 Undesirable Effects:

The product may cause temporary burning and irritation on being

applied into the eye. If pain, changes in vision, continued redness or irritation of the eye is experienced, or if the condition worsens or persists, consult an ophthalmologist.

4.9 Overdose and special antidotes:

None known

5-Pharmacological Properties :

Sodium Chloride in **Salacyn 5% Eye Drops** is used as an iso-osmotic agent, which contains a buffer and may contain suitable anti-microbial and stabilizing agents.

Sodium Chloride is the principal salt involved in maintaining the osmotic tension of the blood and tissues; changes in osmotic tension influence the movement of fluids and diffusion of salts in cellular tissues.

Solutions containing sodium chloride are extensively used for the prevention or correction of fluid and electrolyte deficits or imbalance in a wide range of clinical situations. Oral administration may be effective but usually such solutions must be given intravenously.

Ref. Martindale 28th edition, p. 636

Isotonic or hypotonic (0.18 and 0.45%) sodium chloride solutions may be given in certain circumstances for fluid replacement and hypernatraemia. Sodium Chloride 0.9% being isotonic, is a useful fluid for sterile irrigations and wound cleansing.

Ref. Martindale 31st edition, p. 1184

PHARMACOKINETICS

Sodium Chloride is well absorbed from the gastro intestinal tract. Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption. Small amount of sodium are lost in faeces and sweat.

Ref. Martindale 31st edition, p. 1184

6-Pharmaceutical Particulars:

6.1 List of excipients

1. Sorbic Acid USP
2. Sodium Borate NF
3. Boric Acid NF
4. Potassium Chloride USP
5. Disodium Edetate USP
6. Benzalkonium Chloride 50 % Solution NF
7. 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 20°C – 25°C.

6.5 Nature and contents of container :

10 mL, packed in LDPE a white bottle and clear plug with HDPE white cap

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

8-Marketing Authorization Numbers: **A4-3879**

9-Date of first authorization/renewal of the authorization: **25 March 2020**

10-Date of revision of the text : --