

SUMMARY OF PRODUCT CHARACTERISTIC

1. Name of the medicinal product

Zaline klean[®]

2. Qualitative and quantitative declaration

Each single dose unit container contains sodium chloride 0.9 g/100 ml

3. Pharmaceutical form

Irrigation solution

Zaline klean[®] Irrigation Solution is a clear, colorless, sterile, isotonic, and preservative-free solution for irrigation.

4. Clinical particulars

4.1 Therapeutic indications

- Use for rinsing and cleaning purposes which use of a sterile, non-pyrogenic saline solution.
- Use as nasal drops.
- Use for irrigation as directed by your doctor e.g. eye irrigation.
- Use for cleaning wounds.

4.2 Posology and method of administration

Zaline klean[®] must not be administered by parenteral injection. The use of aseptic technique is essential when the irrigation solution is used for irrigation of body cavities, wounds and urethral catheters.

Dosage

Dosage of Zaline klean[®] depends on the capacity or surface area of the structure to be irrigated and the nature of the procedure. When it is used as a diluent or vehicle for other drugs, the manufacturer's recommendations should be followed. Specialised references should be consulted for specific information on the compatibility of additives.

4.3 Contraindications

Zaline klean[®] should not be used for irrigation during electrosurgical procedures.

Zaline klean[®] should not be used for intravenous injection or injection by other usual parenteral routes.

Do not use unless the solution is clear and the seal is intact.

4.4 Special warnings and precautions for use

For external use only. Not for injection, for irrigation only.

4.5 Interaction with other medicinal products and other forms of interaction

- Additives may be incompatible with Zaline klean[®]
- Product Information documents of intended medications for mixing should be checked beforehand to avoid incompatibility.
- Do not store Zaline klean[®] after mixing with any additives.
- Co-medication of drugs induction sodium retention may exacerbate any systemic effects caused by this irrigation solution.

4.6 Pregnancy and lactation

No data available.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

No data available.

4.9 Overdose

No data available.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of action

Zaline klean[®] exerts a mechanical cleansing action for sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters and surgical drainage tubes. It also acts as diluent or vehicle for other pharmaceutical preparations.

Sodium is the major cation of the extracellular fluid and functions principally in the control of water distribution, fluid and electrolyte balance and osmotic pressure of body fluids. Chloride the major extracellular anion, closely follows the physiological disposition of the sodium cation in the maintenance of acid-base balance, isotonicity and electrodynamic characteristics of cells.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity

The active ingredients sodium and chloride are not mutagenic.

Carcinogenicity

The active ingredients sodium and chloride are not carcinogenic



6. Pharmaceutical particulars

6.1 List of excipients

None

6.2 Incompatibilities

- Additives may be incompatible with Zaline klean[®].
- Product Information documents of intended medications for mixing should be checked beforehand to avoid incompatibility.
- Do not store Zaline klean[®] after mixing with any additives.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

Clear plastic container (LPDE) of 3, 5 and 10 mL with a paper box of 5, 10, 20, 50 and 100 tubes.

7. Manufacturer

PHARMA INNOVA CO., LTD.

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8. Marketing authorization number(s)

xx xxx/xx

9. Date of first authorization/ renewal of the authorization

DD/MM/YYYY

10. Date of revision of the text

23 February 2024