

Summary of Product Characteristics (SmPC)

SEISHOKU (SODIUM CHLORIDE 0.9% IRRIGATION SOLUTION)

1. Name of the medicine

SEISHOKU (Sodium chloride 0.9%^w/v irrigation solution)

2. Qualitative and quantitative composition

Each 1 mL of Sodium Chloride 0.9% contains 9 mg of sodium chloride.

3. Pharmaceutical form

Irrigation solution

Sodium Chloride 0.9% Irrigation Solution is a clear, colorless, sterile, isotonic, and preservative-free solution for irrigation.

4. Clinical particulars

4.1 Therapeutic indications

For wounds irrigation.

4.2 Dose and method of administration

Dosage of Sodium Chloride Irrigation Solution depends on the capacity or surface area of the structure to be irrigated and the nature of the procedure.

4.3 Contraindications

No contraindications

4.4 Special warnings and precautions for use

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

4.5 Interactions with other medicines and other forms of interactions

No data available

4.6 Fertility, pregnancy and lactation

No data available

4.7 Effects on ability to drive and use machines

No data available

4.8 Adverse effects (undesirable effects)

No data available

4.9 Overdose

No data available

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium Chloride 0.9% Irrigation Solution exerts a mechanical cleansing action for sterile irrigation of wounds.

5.2 Pharmacokinetic properties

No data available

5.3 Preclinical safety data

No data available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

6.2 Incompatibilities

No data available

6.3 Shelf life

5 years for 1000 mL plastic bottle

30 month for 150 mL plastic bottle

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

Sodium chloride 0.9% Irrigation solution (Sterile) is presented in plastic bottle 150 mL and 1000 mL.

7. Manufacturer

Thai Otsuka Pharmaceutical Co., Ltd.

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8. Drug license No.

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9. Date of First Approval

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10. Date of revision

First version : 31 August 2020