**Revised: August 2019 (14th version)
*Revised: April 2014

Standard Commodity Classification No. of Japan:
873311

Isotonic Sodium Chloride Solution

Saline PL "FUSO"

Storage : Store at room temperature.
Expiration date: Do not use after the expiration date indicated on the outer package.
Caution : See the section "PRECAUTIONS FOR HANDLING"
Prescription drug:
(Caution – Use only pursuant to the prescription issued of physician, etc.)

	50 mL	100 mL
Approval No.	21900AMX01473	
Date of listing in the NHI reimbursement price	July 1988	October 1987
Date of initial marketing in Japan	October 2003	October 1987
Re-evaluation result	October 1977	

DESCRIPTION

1. Composition

Saline PL "FUSO" is a clear, colorless aqueous injection solution containing 0.9 W/V% sodium chloride in one polyethylene ampoule, plastic bottle, or plastic bag. The solution is clear and colorless.

[Electrolyte concentration]

Na^+	Cl^-
154.0	154.0

(mEq/L: theoretical value)

2. Formulation properties

Saline PL "FUSO" is a clear, colorless aqueous injection solution in a polyethylene container with a weak salt taste.
pH: 4.5 to 8.0

INDICATIONS

◇ Extracellular fluid depletion, sodium depletion, and chloral depletion
◇ Dissolution and dilution agent for injectable drug
◇ Washing and poultice of skin, wound surface, and mucous membrane, and as a mouthwash and spray inhalant, bronchial mucous membrane washing and sputum discharge promotion
◇ Cleaning of medical instruments

DOSAGE AND ADMINISTRATION

Injection

1) The usual dosage is 20 to 1000 mL by subcutaneous, intravenous, or intravenous infusion. The dose may be adjusted according to the patient's age and symptoms.
2) An appropriate amount is taken and used for dilution and dissolution of injectable medicinal products.

External use

1) It is used for washing and poultice of skin, wound surface and mucous membrane.
2) Used for gargling and spray inhalation.

The others

Used for cleaning medical instruments.

PRECAUTIONS

1. Careful Administration: The drug should be administered with caution to the following patients

(1) Patients with dysfunction of the heart or circulatory system [There is a risk of increasing the volume of circulating blood, which may place a burden on the heart and worsen symptoms.]
(2) Patients with renal impairment [It is easy to fall into overdose of water and sodium chloride, and symptoms may be aggravated.]

2. Adverse Drug Reactions

This product has not been subjected to any studies to clarify the frequency of adverse drug reactions, such as results of use surveys.
If any adverse reactions are observed, appropriate measures such as discontinuation of administration should be taken.

	Frequency Unknown
Massive and rapid administration	Rapid administration of large doses may cause serum electrolyte abnormalities, congestion Hematogenous heart failure, edema, acidosis

3 Administration to the elderly

In general, the physiological functions of the elderly are impaired, so the dose should be reduced slowly and with caution.

4. Precautions for Use

(1) Precautions before dosing: When used as a dissolution and dilution agent for injection, make sure that the saline is appropriate.
(2) Pre-dose:
  1) When administering the drug, care should be taken to prevent infection (disinfection of the patient's skin and equipment).
  2) Warm the product to about body temperature before use.
  3) Use immediately after opening the package, and never use the remaining liquid.
(3) Subcutaneous injection: For subcutaneous injection, the following points should be taken into consideration in order to avoid effects on tissues and nerves.
  1) Care should be taken to avoid areas of nerve travel.
  2) When injecting repeatedly, the injection site should be changed, for example, alternating right and left injections. It is recommended that infants, children, and pediatric patients should not use the injection needle repeatedly.
  3) When the injection needle is inserted, the patient may complain of severe pain or may experience a backflow of blood. If it is observed, remove the needle immediately and inject at a different site.
(4) During intravenous injection: administer slowly intravenously.

PHARMACOKINETICS

Sodium chloride accounts for more than 90% of the inorganic components of serum and is a major factor in maintaining the osmotic pressure of the extracellular fluid[1,2].

Saline is a sodium chloride solution that is nearly isotonic to the extracellular fluid and is administered to maintain an effective extracellular fluid volume and stabilize circulation in dehydration patients who are deficient in water and electrolytes[3].

Because it is not cytotoxic, it is used as a solvent for cleaning skin and mucous membranes and for medicines, and spray inhalation is used to promote liquefaction and expulsion of viscous sputum[1,3].

PHYSICAL AND CHEMICAL FINDINGS ON ACTIVE INGREDIENTS

Generic name: sodium chloride
Chemical name: sodium chloride
Molecular formula: NaCl
Molecular weight: 58.44
Character: Colorless or white crystals or crystalline powder. Soluble in water, insoluble in ethanol (99.5).

PRECAUTIONS FOR HANDLING

50mL, 100mL:

1) No need for ventilating needles. (Aeration needle may be required depending on the injection volume.)
2) When used as an infusion solution, do not use a connecting tube for continuous administration. When continuous administration is used, use a Y-type set.
3) Do not use the product if the solution has leaked out of the bag or become turbid.
4) Do not use the product if the over-seal (applied to prevent soiling of the rubber stopper) should have been peeled off.
5) In puncturing a rubber stopper provided on this product, keep the needle perpendicular to the surface of the stopper and slowly push it forward. If the needle is slanted, it may cause contamination of the solution with (core) rubber pieces or may damage the injection port, thereby inducing leakage of the solution.
6) Use the graduations on the infusion bag only to make a rough estimate of the volume administered.

** PACKAGING *

50 mL: Boxes of 10 plastic bottles
100 mL: Boxes of 10 plastic bottles

PL means a polyethylene ampoule developed specifically by FUSO Pharmaceutical Industries, Ltd.

REFERENCES

1) The United States Dispensatory, 27th ed., 1050 (1973)
2) Martindale: The Extra Pharmacopoeia, 29 th ed., 1039 (1989)
3) AMA Drug Evaluations, 3rd ed. ed., 233, 65 9 (1977)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Drug Information Office

Research and Development Center

FUSO Pharmaceutical Industries, Ltd.

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