SODIUM CHLORIDE- sodium chloride injection, solution
SOLA Pharmaceuticals, LLC

0.9% Sodium Chloride Injection, USP
in FLEBOFLEX and FLEBOFLEX LUER Plastic Container

DESCRIPTION

Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents. The pH ranges from 4.5 to 7.0. Composition, osmolarity, and ionic concentration are shown below:

0.9% Sodium Chloride Injection, USP contains 9 g/L Sodium Chloride, USP (NaCl) with an osmolarity of 308 mOsmol/L (calc). It contains 154 mEq/L sodium and 154 mEq/L chloride.

The FLEBOFLEX and FLEBOFLEX LUER plastic containers are fabricated from latex-free polyolefins or polypropylene plastic materials. The solution contact materials do not contain PVC, DEHP, or other plasticizers. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. The suitability of the container materials has been established through biological evaluations, which have shown the containers pass Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container systems.

CLINICAL PHARMACOLOGY

Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.

CONTRAINDICATIONS

None known.

WARNINGS

Hypersensitivity

Hypersensitivity and infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus have been reported with 0.9% Sodium Chloride Injection,

USP.

Stop the infusion immediately if signs or symptoms of a hypersensitivity reaction develop, such as tachycardia, chest pain, dyspnea and flushing. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Electrolyte Imbalances

Fluid Overload

Depending on the volume and rate of infusion, and the patient's underlying clinical condition, the intravenous administration of Sodium Chloride Injection, USP can cause fluid disturbances such as overhydration/hypervolemia and congested states, including pulmonary congestion and edema.

Avoid 0.9% Sodium Chloride Injection, USP in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, electrolyte concentrations, and acid base balance, as needed and especially during prolonged use.

Hyponatremia

Sodium Chloride Injection, USP may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

The risk of hospital-acquired hyponatremia is increased in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH) treated with high volume of Sodium Chloride Injection, USP.

The risk for hyponatremia is increased in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as diuretics, certain antiepileptic and psychotropic medications). See **Drug Interactions.**

Patients at increased risk for developing complications of hyponatremia such as hyponatremic encephalopathy, include pediatric patients, women (in particular pre-menopausal women), patients with hypoxemia, and patients with underlying central nervous system disease. Avoid Sodium Chloride Injection, USP in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications. Brain adaptations reducing risk of cerebral edema make the brain vulnerable to injury when chronic hyponatremia is too rapidly corrected, which is known as osmotic demyelination syndrome (ODS). To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

Hypernatremia

Hypernatremia may occur with Sodium Chloride Injection, USP. Conditions that may increase the risk of hypernatremia, fluid overload and edema (central and peripheral), include patients with: primary hyperaldosteronism; secondary hyperaldosteronism associated with, for example, hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis); and pre-eclampsia.

Certain medications such as corticosteroids or corticotropin, may also increase risk of sodium and fluid retention, see **Drug Interactions**.

Avoid Sodium Chloride Injection, USP in patients with, or at risk for, hypernatremia. If use cannot be avoided, monitor serum sodium concentrations.

Rapid correction of hypernatremia is potentially dangerous with risk of serious neurologic complications. Excessively rapid correction of hypernatremia is also associated with a risk for serious neurologic complications such as osmotic demyelination syndrome (ODS) with risk of seizures and cerebral edema.

PRECAUTIONS

Patients with Severe Renal Impairment

Administration of Sodium Chloride Injection, USP in patients with or at risk of severe renal impairment, may result in hypernatremia and/or fluid overload (see **Warnings**). Avoid Sodium Chloride Injection, USP in patients with severe renal impairment or conditions that may cause sodium and/or potassium retention, fluid overload, or edema. If use cannot be avoided, monitor patients with severe renal impairment for development of these adverse reactions.

Drug Interactions

Other Products that Affect Fluid and/or Electrolyte Balance
Administration of Sodium Chloride Injection, USP to patients treated concomitantly with drugs associated with sodium and fluid retention may increase the risk of hypernatremia and volume overload. Avoid use of Sodium Chloride Injection, USP in patients receiving such products, such as corticosteroids or corticotropin. If use cannot be avoided, monitor serum electrolytes, fluid balance and acid-base balance.

Lithium
Renal sodium and lithium clearance may be increased during administration of 0.9% Sodium Chloride Injection, USP. Monitor serum lithium concentrations during concomitant use.

Other Drugs that Increase the Risk of Hyponatremia
Administration of Sodium Chloride Injection, USP in patients treated concomitantly with medications associated with hyponatremia may increase the risk of developing hyponatremia.

Avoid use of Sodium Chloride Injection, USP in patients receiving products, such as diuretics, and certain antiepileptic and psychotropic medications. Drugs that increase the vasopressin effect reduce renal electrolyte free water excretion and may also increase the risk of hyponatremia following treatment with intravenous fluids. If use cannot be avoided, monitor serum sodium concentrations.

Pregnancy

There are no adequate and well controlled studies with Sodium Chloride Injection, USP in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman. Sodium Chloride Injection, USP should

be given during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

It is not known whether this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when Sodium Chloride Injection, USP is administered to a nursing woman.

Pediatric Use

The use of Sodium Chloride Injection, USP in pediatric patients is based on clinical practice. (See **Dosage and Administration**).

Closely monitor plasma electrolyte concentrations in pediatric patients who may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of Sodium Chloride Injection, USP may result in increased serum osmolality and risk of intracerebral hemorrhage.

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy.

Geriatric Use

Geriatric patients are at increased risk of developing electrolyte imbalances. Sodium Chloride Injection, USP is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Therefore, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Consider monitoring renal function in elderly patients.

ADVERSE REACTIONS

Post-Marketing Adverse Reactions

The following adverse reactions have been identified during post approval use of Sodium Chloride Injection, USP. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been reported in the post-marketing experience during use of 0.9% Sodium Chloride Injection, USP and include the following:

General disorders and administration site conditions: Infusion site erythema, injection site streaking, burning sensation, and infusion site urticaria.

Hypersensitvity reactions: Hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus.

Metabolism and nutrition disorders: Hypernatremia, hyponatremia, hyperchloremic metabolic acidosis.

Nervous System Disorders: Hyponatremic encephalopathy.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

Excessive administration of 0.9% Sodium Chloride Injection, USP can cause hypernatremia. Hypernatremia can lead to CNS manifestations, including seizures, coma, cerebral edema and death.

Excessive administration of Sodium Chloride Injection, USP can cause fluid overload (which can lead to pulmonary and/or peripheral edema). See **Warnings** and **Adverse Reactions.**

When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment.

Interventions include discontinuation of Sodium Chloride Injection, USP administration, dose reduction, and other measures as indicated for the specific clinical constellation (e.g., monitoring of fluid balance, electrolyte concentrations and acid base balance).

DOSAGE AND ADMINISTRATION

Important Administration Instructions

- Sodium Chloride Injection, USP is intended for intravenous administration using sterile equipment.
- Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.
- Set the vent to the closed position on a vented intravenous administration set to prevent air embolism.
- Use a dedicated line without any connections to avoid air embolism.
- Do not pressurize intravenous solutions contained in flexible plastic containers to increase flow rates in order to avoid air embolism due to incomplete evacuation of residual air in the container.
- Prior to infusion, visually inspect the solution for particulate matter and discoloration. The solution should be clear and there should be no precipitates. Do not administer unless solution is clear, and container is undamaged.

Dosing Information

The choice of product, dosage, volume, rate, and duration of administration is dependent upon the age, weight and clinical condition of the patient and concomitant therapy, and administration should be determined by a physician experienced in intravenous fluid therapy.

Introduction of Additives

Additives may be incompatible.

Evaluate all additions to the plastic container for compatibility and stability of the resulting preparation. Consult with a pharmacist, if available.

If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use. Do not store solutions containing additives. Discard any unused portion.

HOW SUPPLIED

The available sizes of 0.9% Sodium Chloride Injection, USP are shown below:

Size (mL)	**NDC**
Fleboflex bags:	
50 (115 units in one carton)	70512-841-06
100 (70 units in one carton)	70512-841-11
250 (28 units in one carton)	70512-841-26
500 (20 units in one carton)	70512-841-51
1000 (10 units in one carton)	70512-841-61
Fleboflex Luer bags:	
50 (90 units in one carton)	Not distributed by SOLA Pharmaceuticals LLC
100 (50 units in one carton)	Not distributed by SOLA Pharmaceuticals LLC
250 (32 units in one carton)	Not distributed by SOLA Pharmaceuticals LLC
500 (24 units in one carton)	Not distributed by SOLA Pharmaceuticals LLC
1000 (10 units in one carton)	Not distributed by SOLA Pharmaceuticals LLC

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at 20° to 25°C (68° to 77°F); excursions are permitted between 15° to 30°C (59° to 86°F). [see USP Controlled Room Temperature.]Store unit in moisture barrier overwrap. Brief exposure up to 40°C (104°F) does not adversely affect the product.

DIRECTIONS FOR USE OF FLEBOFLEX AND FLEBOFLEX LUER PLASTIC CONTAINERS

For Information on Risk of Air Embolism – see **Dosage and Administration**.

To Open

Peel off the overwrap and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration
1. Suspend container from eyelet support.
2. Fleboflex bags: Remove plastic protector from outlet port at bottom of container.
   Fleboflex Luer bags: Break the twist-off administration port by means of torsion.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication
Additives may be incompatible.

To add medication before solution administration
1. Prepare medication site.
2. Fleboflex bags: Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
   Fleboflex Luer bags: Using syringe or vial, connect to the needle-free medication port and inject.
3. Mix solution and medication thoroughly.

To add medication during solution administration
1. Close clamp on the set.
2. Prepare medication site.
3. Fleboflex bags: Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
   Fleboflex Luer bags: Using syringe or vial, connect to the needle-free medication port and inject.
4. Remove container from intravenous pole and/or turn to an upright position.
5. Mix solution and medication thoroughly.
6. Return container to in-use position and continue administration.

Distributed by:
SOLA Pharmaceuticals LLC
Baton Rouge, LA 70810

Manufactured by: **Laboratorios Grifols, S.A.**
30565 Murcia - SPAIN

Printed in SPAIN

Rev. 08/2020

3064796 (Internal reference)

SOLA Pharmaceuticals

PACKAGE LABEL

NDC 70512-841-51

0.9% Sodium Chloride
Injection, USP

500 mL

Fleboflex Container

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F).
[see USP Controlled Room Temperature.] Avoid excessive heat.

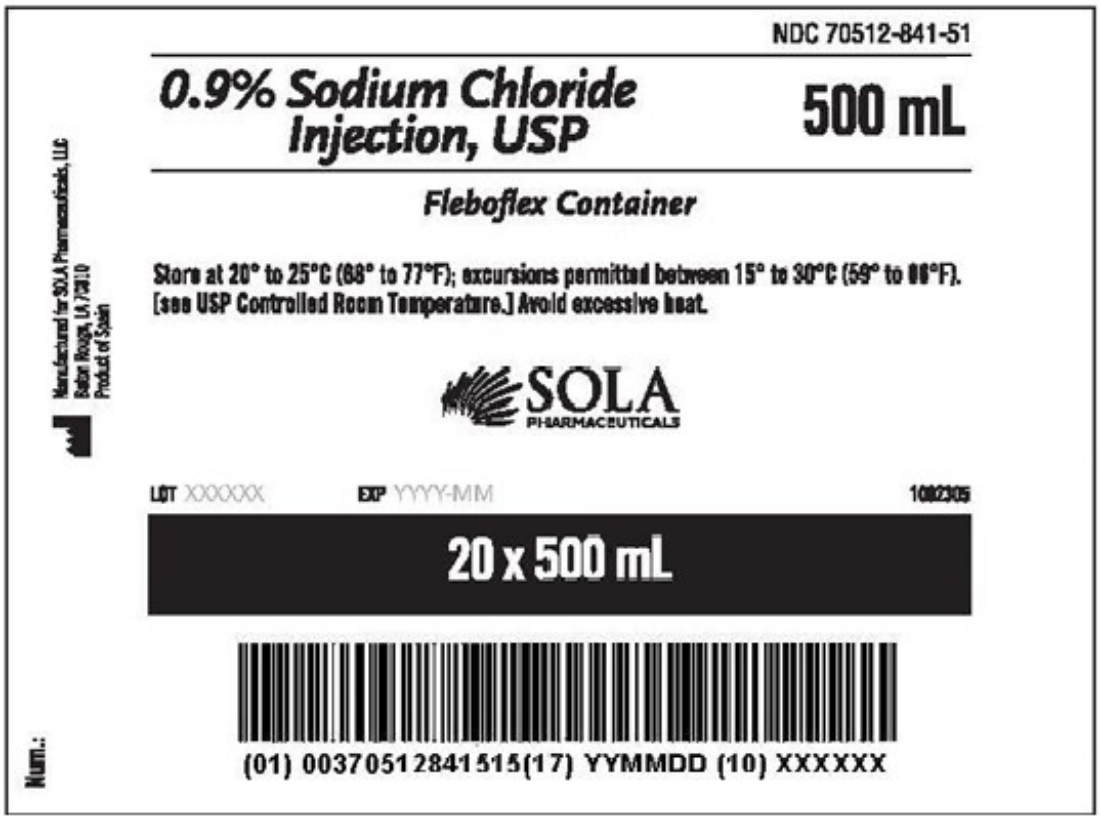
SOLA
PHARMACEUTICALS

LOT XXXXXX **EXP** YYYY-MM **1002305**

20 x 500 mL

Num.:

Manufactured for SOLA Pharmaceuticals, LLC
Baton Rouge, LA 70810
Product of Spain



NDC 70512-841-50

0.9% Sodium Chloride
Injection, USP

500 mL

For intravenous use

Rx Only

Single dose container

Each 100 ml contains 900 mg Sodium Chloride USP; pH 4.5 to 7.0 Sodium 154 mEq/L Chloride 154 mEq/L; Osmolarity 308 mOsmol/L (calc)

Sterile Non pyrogenic. Dosage intravenously as directed by a physician. See directions. Cautions: Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found. Must not be used in series connections. Do not use unless solution is clear. Additives may be incompatible. Consult with pharmacist if available. When introducing additives, use aseptic technique. Mix thoroughly. Do not store.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F). [see USP Controlled Room Temperature.] Store unit in moisture barrier overwrap. Brief exposure up to 40°C (104°F) does not adversely affect the product. Avoid excessive heat. Read package insert for full information.

Grifols and Fleboflex are trademarks of Grifols, S.A.

Manufactured for SOLA Pharmaceuticals LLC.
Baton Rouge, LA 70810
Product of Spain

Fleboflex Container
(PVC-free and DEHP-free)
The container closure is not made with natural rubber latex.

SOLA

4000897

LOT XXXXXX
EXP YYYY-MM

NDC 70512-841-50

0.9% Sodium Chloride Injection, USP

500 mL

For intravenous use **Rx Only**

Single dose container

Each 100 mL contains 900 mg Sodium Chloride USP; pH 4.5 to 7.0
Sodium 154 mEq/L Chloride 154 mEq/L; Osmolarity 308 mOsmol/L (calc)

Sterile Non pyrogenic. Dosage intravenously as directed by a physician. See directions. Cautions: Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found. Must not be used in series connections. Do not use unless solution is clear. Additives may be incompatible. Consult with pharmacist if available. When introducing additives, use aseptic technique. Mix thoroughly. Do not store.
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Manufactured for SOLA Pharmaceuticals LLC.
Baton Rouge, LA 70810
Product of Spain

Fleboflex Container

4000897

(PVC-free and DEHP-free)
The container closure is not made with natural rubber latex.

SOLA

(01)00370512841508

LOT XXXXXX
EXP YYYY-MM
INTERNAL REFERENCE

(17)YYMMDD(10)XXXXXX

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70512-841
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Chloride (UNII: 451W47IQ8X) (Chloride Ion - UNII:Q32ZN48698, Sodium Cation - UNII:LYR4M0NH37)	Sodium Chloride	9 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70512-841-06	115 in 1 CARTON	12/20/2023	
1	NDC:70512-841-05	50 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:70512-841-11	70 in 1 CARTON	12/20/2023	
2	NDC:70512-841-10	100 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:70512-841-26	28 in 1 CARTON	12/20/2023	
3	NDC:70512-841-25	250 mL in 1 BAG; Type 0: Not a Combination Product		
4	NDC:70512-841-51	20 in 1 CARTON	12/20/2023	
4	NDC:70512-841-50	500 mL in 1 BAG; Type 0: Not a Combination Product		
5	NDC:70512-841-61	10 in 1 CARTON	12/20/2023	
5	NDC:70512-841-60	1000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207956	05/25/2017	

Labeler - SOLA Pharmaceuticals, LLC (080121345)

Registrant - LABORATORIOS GRIFOLS SA (461842294)

Establishment

Name	Address	ID/FEI	Business Operations

LABORATORIOS GRIFOLS SA		463720681	manufacture(70512-841) , pack(70512-841) , label(70512-841)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Grifols, S.A.		461842294	analysis(70512-841)

Revised: 6/2024 SOLA Pharmaceuticals, LLC