Sodium Chloride 0.9% Injection, FK Std.

DESCRIPTION
Sodium Chloride 0.9% Injection is a sterile nonpyrogenic intravenous solution that contains no bacteriostatic or antimicrobial agents or added buffers.

Each 100 mL of Sodium Chloride 0.9% Injection contains:

- Sodium chloride: 900 mg
- Water for injection: q.s
- pH adjusted with sodium hydroxide or Hydrochloric acid 25%: q.s

The solution has an osmolarity of 308 mOsmol/L (calc) with 154 mEq/L sodium and 154 mEq/L chloride. The pH is 5.6.

The formula of the active ingredient is:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Molecular Formula</th>
<th>Molecular Weight (g/mol)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Chloride</td>
<td>NaCl</td>
<td>58.44</td>
</tr>
</tbody>
</table>

Table 1. Description of the freeflex® and the freeflex® (plus) systems

<table>
<thead>
<tr>
<th>freeflex® container</th>
<th>freeflex® (plus) container</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESCRIPTION</td>
<td></td>
</tr>
<tr>
<td>• The primary container consists of a bag and two ports with stoppers.</td>
<td>• Same as freeflex® container</td>
</tr>
<tr>
<td>• The secondary packaging is an overwrap.</td>
<td>• Same as freeflex® container</td>
</tr>
<tr>
<td>• The freeflex® plastic container is fabricated from a specially formulated polyolefines multilayer film. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. The freeflex® bags are slightly overfilled. It is guaranteed that the extractable volume conforms at the end of shelf-life. Results of the toxicological evaluation show that the primary materials of the freeflex packaging system do not show any toxic potential even under severe extraction conditions.</td>
<td>• Same as freeflex® container</td>
</tr>
<tr>
<td>PORTS</td>
<td></td>
</tr>
<tr>
<td>• Two ports, with white and blue stoppers capped with tamper-evident covers.</td>
<td>• Two ports, with light blue and blue stoppers capped with tamper-evident covers.</td>
</tr>
<tr>
<td>• The white stopper on the left port, with the arrow pointing towards the bag, is the</td>
<td>• The light blue stopper on the left port, with the arrow pointing towards the bag is</td>
</tr>
<tr>
<td>medication/injection port.</td>
<td>the medication port. It has a threaded Luer lock connector to secure a syringe once the tamper-evident cover is broke-off.</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>• The blue port with the arrow pointing away from the bag is the administration port.</td>
<td>• The blue port with the arrow pointing away from the bag is the administration port.</td>
</tr>
<tr>
<td>• The addition of drugs to freestyle bag via the medication port uses a syringe with a 19 to 22 gauge blunt fill needle to puncture the medication port and inject medication into the bag.</td>
<td>• The addition of drugs to the freestyle® bag via the medication port is needle-free. This can be performed by fastening the syringe to the Luer lock, to inject the medication into the bag. After additions, the medication port can be marked with a permanent red protective cap to indicate medication has been added.</td>
</tr>
</tbody>
</table>

**CLINICAL PHARMACOLOGY**

Sodium Chloride 0.9% Injection provides electrolytes and is a source of water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

**INDICATIONS AND USAGE**

Sodium Chloride 0.9% Injection, 900 mg /100 mL, is indicated as a source of electrolytes and water for hydration.

This product is also designed for use as a diluent and delivery system for intermittent intravenous administration of compatible drug additives. Consult prescribing information for INDICATIONS AND USAGE of drug additives to be administered in this manner.

**CONTRAINDICATIONS**

Sodium Chloride 0.9% injection is contraindicated in fluid overload (hypervolemia) and when the administration of sodium or chloride could be clinically detrimental.

**WARNINGS**

Solutions containing sodium chloride should be used with great care, if at all, in patients with
congestive heart failure, severe renal insufficiency and in clinical states in which there is sodium retention with edema. In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.

**PRECAUTIONS**

**General**

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Special care should be taken when using Sodium Chloride 0.9% Injection in patients with hypokalemia, hypernatremia, hyperchloremia, diseases requiring a restricted sodium intake (e.g. general edema; pulmonary edema; hypertension; pre-eclampsia; renal or cardiovascular insufficiency, with or without congestive heart failure particularly if they are postoperative or elderly. See PRECAUTION, Geriatric Use). Caution must be exercised in the administration of sodium-containing parenteral fluids to patients receiving corticosteroids or corticotrophin.

Fluid overload caused by overdose should be avoided in general. The increased risk of hypervolemia must be taken into consideration, particularly for patients with cardiac insufficiency or severe kidney dysfunctions; posology must be adapted.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Studies with Sodium Chloride 0.9% Injection have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

**Pregnancy**

Teratogenic Effects

Animal reproduction studies have not been conducted with Sodium Chloride 0.9% Injection. It is also not known whether Sodium Chloride 0.9% Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride 0.9% Injection should be given to a pregnant woman only if clearly needed.

**Labor and Delivery**

Studies have not been conducted to evaluate the effects of Sodium Chloride Injection on labor and delivery. As reported in the literature, sodium chloride solutions have been administered during labor and delivery. Caution should be exercised, and the fluid balance, glucose and
electrolyte concentrations and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

**Nursing Mothers**

Because many drugs are excreted in human milk, caution should be exercised when Sodium Chloride 0.9% Injection is administered to a nursing woman.

**Pediatric Use**

Safety and effectiveness of sodium chloride injections in pediatric patients have not been established by adequate and well controlled trials; however, the use of Sodium Chloride solutions in the pediatric population is referenced in the medical literature. All Warnings, Precautions and Adverse Reactions described in this label apply to pediatric patients.

**Geriatric Use**

An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, 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.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

**ADVERSE REACTIONS**

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

These adverse reactions have been reported during administration of electrolyte solutions: hypervolemia and heart failure in patients with cardiac disorder or pulmonary edema (very common); electrolyte disturbances (very common) and edema due to water/sodium overload (unknown frequency). Therefore, frequent monitoring of electrolyte levels is essential.

High doses of fluid can commonly lead to dilution of blood components, e.g. coagulation factors and other plasma proteins, and a decrease of the hematocrit.

Hyponatremia may be associated with edema and exacerbation of congestive heart failure due to the retention of water, resulting in an expanded extracellular fluid volume.

The physician should also be alert to the possibility of adverse reactions associated with the drug additives added to the solution. Prescribing information for drug additives should be consulted.
If any adverse reactions occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid and administration set for examination, if deemed necessary.

OVERDOSAGE

Overdose may lead to hypervolemia with tightened skin, venous stasis, pulmonary or cerebral edema as well as disturbed acid-base and electrolyte balance.

In these cases, the infusion should be stopped immediately and measures must be taken to increase renal elimination by application of fast acting diuretics (e.g. furosemide) and to achieve a corresponding negative balance.

In case of occurring oliguria or anuria fluid withdrawal by hypertonic hemofiltration may be necessary to remove excessive fluid.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

DOSAGE AND ADMINISTRATION

As directed by a physician. The dosage is dependent upon the age, weight and clinical conditions of the patient as well as laboratory determinations.

This solution is for intravenous use only. Use only if solution is clear and container and seals are intact.

In case of large volume application the use of balanced crystalloid solution with reduced chloride content should be considered in order to avoid hyperchloremic acidosis.

There is no specific pediatric dose. The dose is dependent on weight, clinical condition, and laboratory results. Follow recommendations of appropriate pediatric reference text. See PRECAUTIONS, Pediatric Use.

When using this product as a diluent or vehicle for administration of medication, consult the prescribing information of the drug to be used. Addition of medication should be accomplished using aseptic technique in order to assure sterility.

Some additives may be incompatible. Consult with pharmacist. When introducing medication, use aseptic techniques. Mix thoroughly. Do not store.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED
Sodium Chloride 0.9% Injection, is available in 50, 100, 250, 500 and 1000 mL freeflex® and freeflex® plastic containers, that are PVC-free, DEHP-free and latex-free.

<table>
<thead>
<tr>
<th>Packaging</th>
<th>Storage condition</th>
<th>Shelf-Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>freeflex® / freeflex® bags</td>
<td>15 °C – 25 °C</td>
<td>2 years</td>
</tr>
<tr>
<td>(50, 100 mL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>freeflex® / freeflex® bags</td>
<td></td>
<td>3 years</td>
</tr>
<tr>
<td>(250, 500, 1000 mL)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**DIRECTIONS FOR USE**

I. **Infusion Application with freeflex® container**

**WARNINGS:**
Do not administer unless the solution is clear, virtually colourless and the seal is intact

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

From a microbiological point of view, the medicinal product should be used immediately after addition of additives. Do not store. Discard unused portion.

The physician should discontinue the infusion if adverse reactions occur.

**CAUTION:**
Aseptic technique is required including when mixing with medication. This solution is intended for intravenous administration using sterile equipment. When the Sodium Chloride 0.9% Injection is used for intermittent intravenous infusion, the intravenous administration set should be replaced every 24 hours. If Sodium Chloride 0.9% Injection is to be administered as a continuous infusion, then the administration set should be changed every 96 hours or as per hospital practice.

Do not remove the freeflex® IV container from its overwrap until immediately before use.

Before use, perform the following checks: Read the label. Ensure solution is the one ordered and is within the expiration date.

Parenteral drug products should be inspected visually in good light for cloudiness, haze, particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless the solution is clear.

The freeflex® IV container should also be inspected for leakage or damage, ensuring that the seals are intact. Any container which is suspect should not be used. This preservative free solution is intended for single use only. Any unused portion or waste materials should be disposed in accordance with local requirements.
Sodium Chloride 0.9% Injection (900 mg/100 ml) should be used immediately after insertion of the administration set. Do not vent.

Before administering the product in plastic bags to patient, review these directions:

1. Check the solution composition, lot number and expiry date, inspect the container for damage or leakage. If damaged do not use.

2. Place the bag on a clean, flat surface. Peel open over-wrap.

3. Identify the blue infusion port (encircled on the right side). This is the administration port. The white port (on the left side) is the medication port where medication is to be injected.

4. Place and keep the bag on a clean, flat surface. Break off the blue tamper-evident cover from the freeflex® infusion port.
5. Close roller clamp of the administration set. Insert the spike until the clear plastic collar of the port meets the shoulder of the spike.

6. Use a non-vented standard infusion set or if using a vented set, close air inlet.


**To add medication**

**WARNING:** Some additives may be incompatible.

**To add medication before solution administration**

1. Prepare medication site.
2. Using a syringe with a 19 to 22 gauge blunt fill needle, puncture the resealable medication port and inject medication.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
4. Place container to in-use position and begin administration.

**To add medication during solution administration**

1. Close clamp on the set.
2. Prepare medication site.
3. Using a syringe with a 19 to 22 gauge blunt fill needle, puncture the resealable medication port and inject medication.
4. Remove container from IV pole and place in an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
7. Return container to in-use position and continue administration.
II. Needle-Free Drug addition to freeflex® container with a Luer-Lock Syringe

WARNINGS:
Do not administer unless the solution is clear, virtually colourless and the seal is intact

Do not use plastic containers in series connections. Such use could result in an air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

From a microbiological point of view, the medicinal product should be used immediately after addition of additives. Do not store. Discard any unused portion.

The physician should discontinue the infusion if adverse reactions occur.

CAUTION:
Aseptic technique is required including when adding medication. This solution is intended for intravenous administration using sterile equipment. When the Sodium Chloride 0.9% Injection is used for intermittent intravenous infusion, the intravenous administration set should be replaced every 24 hours. If Sodium Chloride 0.9% Injection is to be administered as a continuous infusion, then the administration set should be changed every 96 hours or as per hospital practice.

Do not remove the freeflex® IV container from its overwrap until immediately before use.

Before use, perform the following checks: Read the label. Ensure solution is the one ordered and is within the expiration date.

Parenteral drug products should be inspected visually in good light for cloudiness, haze, particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless the solution is clear.

The freeflex® IV container should also be inspected for leakage or damage, ensuring that the seals are intact. Any container which is suspect should not be used. This preservative free solution is intended for single use only. Any unused portion or waste materials should be disposed of in accordance with local requirements.

Sodium Chloride 0.9% Injection (900 mg/100 ml) should be used immediately after insertion of the administration set. Do not vent.

To add medication
WARNING: Some additives may be incompatible.

To add medication before solution administration and before administering the product in plastic bags to patient, review these directions:
1. Using an aseptic technique and observing standard precautions, prepare a syringe with a Luer-lock.

Place the bag on a clean, flat surface. Remove the overwrap. Identify the light blue freeflex® injection port (encircled on the left side).

2. Break off the light blue tamper evident cover from the freeflex® injection port. The membrane below the light blue cover is sterile – disinfection of the membrane is not necessary.

3. Hold the light blue freeflex® injection port with your fingers behind the finger guard. Connect the luer-lock of the syringe with the injection port of the freeflex® and inject the medication into the bag, then remove the syringe. The rigid port construction supports a safe and convenient handling.

4. If no further additions are required, mark the injection port with the provided red protective cap* to indicate that the bag is filled with a drug and attach the label with detailed information to the bag. *caps cannot be removed once fastened.

5. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

6. Break-off the tamper-evident cover from the blue administration port.

7. Use a non-vented standard administration set or if using a vented set, close air inlet.
8. Close roller clamp of the administration set. Insert the spike until the clear plastic collar of the port meets the shoulder of the spike.

**To add medication during solution administration**

1. Close clamp on the set.
2. Prepare medication site.
3. Fasten the needleless, loaded syringe to the threaded Luer lock connection of the light blue freeflex® medication port and inject medication.
4. Remove container from the IV pole and place in an upright position.
5. Evacuate both ports by tapping and squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
7. Return container to in-use position and continue administration.

### REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 0701E
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

**NOTE:** Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

---

Fresenius Kabi Canada
A division of Calea Ltd.
Mississauga, ON, L4W 4Y3
1-877-953-9002

Date of Preparation: March 8, 2013
Submission Control Number: 154594, 161187

Fresenius Kabi and freeflex are registered trademarks of Fresenius Kabi AG.