

07-19-69-742

Baxter

Sodium Chloride Injection, USP

in AVIVA 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 nominal pH is 5.5 (4.5 to 7.0). Composition, osmolarity, and ionic concentration are shown below:

0.45% Sodium Chloride Injection, USP contains 4.5 g/L Sodium Chloride, USP (NaCl) with an osmolarity of 154 mOsmol/L (calc). It contains 77 mEq/L sodium and 77 mEq/L chloride.

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 flexible container is made with non-latex plastic materials specially designed for a wide range of parenteral drugs including those requiring delivery in containers made of polyolefins or polypropylene. For example, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of paclitaxel. In addition, the AVIVA container system is compatible with and appropriate for use in the admixture and administration of all drugs deemed compatible with existing polyvinyl chloride container systems. The solution contact materials do not contain PVC, DEHP, or other plasticizers.

The suitability of the container materials has been established through biological evaluations, which have shown the container passes Class VI U.S. Pharmacopeia (USP) testing for plastic containers. These tests confirm the biological safety of the container system.

The flexible container is a closed system, and air is prefilled in the container to facilitate drainage. The container does not require entry of external air during administration.

The container has two ports: one is the administration outlet port for attachment of an intravenous administration set and the other port has a medication site for addition of

supplemental medication (*See Directions for Use*). The primary function of the overwrap is to protect the container from the physical environment.

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

Sodium Chloride Injection, USP 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 exists edema with sodium retention.

In patients with diminished renal function, administration of Sodium Chloride Injection, USP may result in sodium retention.

PRECAUTIONS

General

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

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests

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.

Drug Interactions

Caution must be exercised in the administration of Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with Sodium Chloride Injection, USP.

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP. It is also not known whether Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection, USP 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, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted 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.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids (0.45% Sodium Chloride Injection, USP) together with the non-osmotic secretion of ADH may result in hyponatremia in patients with acute volume depletion. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

Geriatric Use

Clinical studies of Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses 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 drug therapy.

This drug 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. 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, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

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.

In addition to the above listed adverse reactions, the following has been reported for 0.45% Sodium Chloride Injection, USP (*see Pediatric Use section*).

- Hyponatremia

DOSAGE AND ADMINISTRATION

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

All injections in AVIVA plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with 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. Do not store solutions containing additives.

HOW SUPPLIED

The available sizes of each injection in AVIVA plastic containers are shown below:

Code	Size (mL)	NDC	Product Name
6E1313	500	0338-6333-03	0.45% Sodium Chloride
6E1314	1000	0338-6333-04	Injection, USP
6E1356	250	0338-6333-02	
6E1322	250	0338-6304-02	0.9% Sodium Chloride
6E1323	500	0338-6304-03	Injection, USP
6E1324	1000	0338-6304-04	

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F); brief exposure up to 40°C (104°F) does not adversely affect the product.

DIRECTIONS FOR USE OF AVIVA PLASTIC CONTAINER

To Open

Tear overwrap down side at slit and remove solution container. Moisture and 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

Caution: Do not use plastic containers in series connections.

Caution: Use only with a non-vented set or a vented set with the vent closed.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
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. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Printed in USA

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For Product Information
1-800-933-0303

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Sodium Chloride Injection, USP

in VIAFLEX 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 is 5.0 (4.5 to 7.0). Composition, osmolarity, and ionic concentration are shown below:

0.45% Sodium Chloride Injection, USP contains 4.5 g/L Sodium Chloride, USP (NaCl) with an osmolarity of 154 mOsmol/L (calc). It contains 77 mEq/L sodium and 77 mEq/L chloride.

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 VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

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

Sodium Chloride Injection, USP 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 exists edema with sodium retention.

The intravenous administration of Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutive states is inversely proportional to the electrolyte concentration of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

In patients with diminished renal function, administration of Sodium Chloride Injection, USP may result in sodium retention.

PRECAUTIONS

General

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.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Laboratory Tests

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.

Drug Interactions

Caution must be exercised in the administration of Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been performed with Sodium Chloride Injection, USP to evaluate the potential for carcinogenesis, mutagenesis, or impairment of fertility.

Pregnancy:

Teratogenic Effects

Pregnancy Category C

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

Nursing Mothers

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

Pediatric Use

The use of Sodium Chloride Injection, USP in pediatric patients is based on clinical practice.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids (0.45% Sodium Chloride Injection, USP) together with the non-osmotic secretion of ADH may result in hyponatremia in patients with acute volume depletion. Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death, therefore acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

Geriatric Use

Clinical studies of Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the 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 drug therapy.

This drug 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. 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.

Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS

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

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.

In addition to the above listed adverse reactions the following has been reported for 0.45% Sodium Chloride Injection, USP (*see Pediatric Use section*):

- Hyponatremia

DOSAGE AND ADMINISTRATION

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

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

All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with 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. Do not store solutions containing additives.

HOW SUPPLIED

The available sizes of each injection in VIAFLEX plastic containers are shown below:

Code	Size (mL)	NDC	Product Name
2B1313	500	0338-0043-03	0.45% Sodium Chloride Injection, USP
2B1314	1000	0338-0043-04	
2B1355	100	0338-1452-48	
2B1356	250	0338-1452-02	
2B1300	25 Quad Pack	0338-0049-10	0.9% Sodium Chloride Injection, USP
	50		
2B1306	Single pack	0338-0049-41	
2B1301	Quad pack	0338-0049-11	
2B1308	Multi pack	0338-0049-31	
	100		
2B1307	Single pack	0338-0049-48	
2B1302	Quad pack	0338-0049-18	
2B1309	Multi pack	0338-0049-38	
2B1321	150	0338-0049-01	
2B1322	250	0338-0049-02	
2B1323	500	0338-0049-03	
2B1324	1000	0338-0049-04	

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F); brief exposure up to 40°C (104°F) does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

To Open

Tear overwrap down side at slit and remove solution container. 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. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

WARNING

Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.

6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

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Ringer's Injection, USP

in VIAFLEX Plastic Container

DESCRIPTION

Ringer's 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 may have been adjusted with sodium hydroxide.

Composition, osmolarity, pH and ionic concentration are shown in Table 1.

Table 1.

	Size (mL)	Composition (g/L)			Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)			
		Sodium Chloride, USP (NaCl)	Calcium Chloride, USP (CaCl ₂ ·2H ₂ O)	Potassium Chloride, USP (KCl)			Sodium	Potassium	Calcium	Chloride
Ringer's Injection, USP	500	8.6	0.33	0.3	309	5.5 (5.0 to 7.5)	147.5	4	4.5	156
	1000									

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

Ringer's 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

Ringer's Injection, USP is indicated as a source of water and electrolytes.

CONTRAINDICATIONS

None known

WARNINGS

Ringer's Injection, USP 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 exists edema with sodium retention.

Ringer's Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Ringer's Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Ringer's Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Ringer's Injection, USP may result in sodium or potassium retention.

PRECAUTIONS

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.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

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.

Caution must be exercised in the administration of Ringer's Injection, USP to patients receiving corticosteroids or corticotropin.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Ringer's Injection, USP. It is also not known whether Ringer's Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ringer's Injection, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use

The use of Ringer's Injection, USP in pediatric patients is based on clinical practice.

Geriatric Use

Clinical studies of Ringer's Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the 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.

Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS

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

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.

DOSAGE AND ADMINISTRATION

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

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

All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with 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. Do not store solutions containing additives.

HOW SUPPLIED

Ringer's Injection, USP in VIAFLEX plastic container is available as follows:

Code	Size (mL)	NDC
2B2303	500	0338-0105-03
2B2304	1000	0338-0105-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

To Open

Tear overwrap down side at slit and remove solution container. 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. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

WARNING: Additives may be incompatible

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

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