POTASSIUM CHLORIDE IN SODIUM CHLORIDE- potassium chloride and sodium chloride injection, solution
Baxter Healthcare Company

Potassium Chloride in Sodium Chloride Injection, USP
in Plastic Container
VIAFLEX Plus Container

DESCRIPTION

Potassium Chloride in Sodium Chloride Injection, USP is a sterile, nonpyrogenic, solution for fluid and electrolyte replenishment in a single dose container for intravenous administration. It contains no antimicrobial agents. 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)	Potassium Chloride, USP (KCl)			Sodium	**Potassium**	Chloride
20 mEq/L Potassium Chloride in 0.45% Sodium Chloride Injection, USP	1000	4.5	1.5	194	5.5 (3.5 to 6.5)	77	**20**	97
20 mEq/L Potassium Chloride in 0.9% Sodium Chloride Injection, USP	1000	9	1.5	348	5.5 (3.5 to 6.5)	154	**20**	174
40 mEq/L Potassium Chloride in 0.9% Sodium Chloride Injection, USP	1000	9	3	388	5.5 (3.5 to 6.5)	154	**40**	194

* Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.

The VIAFLEX Plus plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). VIAFLEX Plus on the container indicates the presence of a drug additive in a drug vehicle. The VIAFLEX Plus plastic container system utilizes the same container as the VIAFLEX plastic container system. 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

Potassium Chloride in 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

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

CONTRAINDICATIONS

Potassium Chloride in Sodium Chloride Injection, USP is contraindicated in patients with:

- Known hypersensitivity to potassium chloride and/or sodium chloride (see WARNINGS).
- Clinically significant hyperkalemia (see WARNINGS).

WARNINGS

Hypersensitivity

Hypersensitivity and infusion reactions, including anaphylaxis and chills, have been reported with products containing potassium chloride and sodium chloride. Stop the infusion immediately if signs or symptoms of a hypersensitivity or infusion reaction develops. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Electrolyte Imbalances

Hyperkalemia

Potassium-containing solutions, including Potassium Chloride in Sodium Chloride Injection, USP may increase the risk of hyperkalemia. Hyperkalemia can be asymptomatic and manifest only by increased serum potassium concentrations and/or characteristic electrocardiographic (ECG) changes. Cardiac conduction disorders

(including complete heart block) and other cardiac arrhythmias, some fatal, can develop at any time during hyperkalemia. Continuous electrocardiogram (ECG) monitoring may be necessary to aid in the detection of cardiac arrhythmias due to hyperkalemia (see ADVERSE REACTIONS).

To avoid life threatening hyperkalemia, do not administer Potassium Chloride in Sodium Chloride Injection, USP as an intravenous push (i.e., intravenous injection manually with a syringe connected to the intravenous access) without a quantitative infusion device.

Patients at increased risk of developing hyperkalemia and cardiac arrhythmias include those:

- with conditions predisposing to hyperkalemia and/or associated with increased sensitivity to potassium, such as patients with severe renal impairment, acute dehydration, extensive tissue injury or burns, certain cardiac disorders such as congestive heart failure or atrioventricular (AV) block (especially if they receive digoxin).
- who are at risk of experiencing hyperosmolality, acidosis, or undergoing correction of alkalosis (conditions associated with a shift of potassium from intracellular to extracellular space).
- treated concurrently or recently with agents or products that can cause or increase the risk of hyperkalemia (see DRUG INTERACTIONS).
- with cardiac arrhythmias.

Avoid use of Potassium Chloride in Sodium Chloride Injection, USP in patients with, or at risk for, hyperkalemia. If use cannot be avoided, use a product with a low amount of potassium chloride, infuse slowly and monitor serum potassium concentrations and ECGs.

Hypernatremia and Hyperchloremia

Electrolyte imbalances such as hypernatremia, hyperchloremia, and metabolic acidosis may occur with Potassium Chloride in 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 Potassium Chloride in Sodium Chloride Injection, USP in patients with, or at risk for, hypernatremia or hyperchloremia. If use cannot be avoided, monitor serum sodium and chloride concentrations and acid-base balance.

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.

Hyponatremia

Potassium Chloride in 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 hypotonic Potassium Chloride in 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, premenopausal women), patients with hypoxemia, and patients with underlying central nervous system disease. Avoid Potassium Chloride in 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.

Fluid Overload

Depending on the volume and rate of infusion, and the patient’s underlying clinical condition, the intravenous administration of Potassium Chloride in Sodium Chloride Injection, USP can cause electrolyte disturbances such as overhydration/hypervolemia and congested states including central (e.g., pulmonary edema) and peripheral edema.

Avoid Potassium Chloride in 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.

PRECAUTIONS

Patients with Severe Renal Impairment

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

Drug Interactions

Lithium

Renal sodium and lithium clearance may be increased during administration of Potassium Chloride in Sodium Chloride Injection, USP and result in decreased lithium concentrations. Monitor serum lithium concentrations during concomitant use.

Other Products that Cause Hyperkalemia

Administration of Potassium Chloride in Sodium Chloride Injection, USP in patients treated concurrently or recently with products that are associated with hyperkalemia increases the risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia. Avoid use of Potassium Chloride in Sodium Chloride Injection, USP in patients receiving such products (e.g., potassium sparing diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, or the immunosuppressants cyclosporine and tacrolimus). If use cannot be avoided, monitor serum potassium concentrations.

Other Products that Affect Fluid and/or Electrolyte Balance

Administration of Potassium Chloride in Sodium Chloride Injection, USP in patients treated concomitantly with medications associated with sodium and fluid retention may increase the risk of hypernatremia and volume overload. Avoid use of Potassium Chloride in 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.

Other Drugs that Increase the Risk of Hyponatremia

Administration of Potassium Chloride in Sodium Chloride Injection, USP in patients treated concomitantly with medications associated with hyponatremia may increase the risk of developing hyponatremia.

Avoid use of Potassium Chloride in 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 from the use of Potassium Chloride in Sodium Chloride Injection, USP in pregnant or lactating women and animal reproduction studies have not been conducted with this drug. Therefore, it is also not known whether Potassium Chloride in Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in Sodium Chloride Injection, USP should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus.

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 Potassium Chloride in Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

The use of Potassium Chloride in Sodium Chloride Injection, USP in pediatric patients is based on clinical practice. (See DOSAGE AND ADMINISTRATION). Safety and

effectiveness of Potassium Chloride in Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well-controlled studies.

Pediatric patients are at increased risk of developing hyponatremia as well as for developing encephalopathy as a complication of hyponatremia (see WARNINGS).

Geriatric Use

Geriatric patients are at increased risk of developing electrolyte imbalances. Potassium Chloride in 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

The following adverse reactions associated with the use of Potassium Chloride in Sodium Chloride Injection, USP were identified in clinical trials or postmarketing reports. Because postmarketing reactions were reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency, reliably, or to establish a causal relationship to drug exposure.
General disorders and administration site conditions: Chills, and infusion site pain.
Hypersensitivity reactions: generalized papules and erythema, rash, fever, vomiting, hypertension, tachycardia.
Metabolism and nutrition disorders: Hyperkalemia, hyponatremia, hypernatremia, hyperchloremia acidosis, fluid overload.
Cardiac disorders: Cardiac arrest as a manifestation of rapid intravenous administration and/or of hyperkalemia.
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

An increased infusion rate of Potassium Chloride in Sodium Chloride Injection, USP can cause:

- hyperkalemia, manifestations may include disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation.
  The presence of any ECG findings that are suspected to be caused by hyperkalemia should be considered a medical emergency.
  If hyperkalemia is present or suspected, discontinue the infusion immediately and institute close ECG, laboratory and other monitoring and, as necessary, corrective therapy to reduce serum potassium concentrations.
  Muscle weakness (up to and including muscular and respiratory paralysis,

paresthesia of extremities) may occur as a complication of hyperkalemia.
- hyponatremia, manifestations may include seizures, coma, cerebral edema and death).
- hypernatremia, especially in patients with severe renal impairment.
- hypotension.
- gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain).
- fluid overload (which can lead to central 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 Potassium Chloride in 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

- Potassium Chloride in Sodium Chloride Injection, USP is intended for intravenous infusion using sterile equipment.
- To avoid life threatening hyperkalemia, do not administer Potassium Chloride in Sodium Chloride Injection, USP as an intravenous push (i.e., intravenous injection manually with a syringe connected to the intravenous access) without a quantitative infusion device (see WARNINGS).
- 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.
- The choice of a central or peripheral venous route of infusion should depend on the osmolarity of the final infusate. Solutions with osmolarity of greater than or equal to approximately 900 mOsm/L must be infused through a central catheter.
- 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.
- Use of final filter is recommended during administration of all parenteral solutions, where possible.

Dosing Information

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

Additional electrolyte supplementation may be indicated according to the clinical needs of the patient. Additives can be introduced to the container; however, some

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. After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use. Mix thoroughly when additives have been introduced. Do not store solutions containing additives. Discard any unused portion.

Rapid correction of hyponatremia and hypernatremia is potentially dangerous (risk of serious neurologic complications). To avoid complications such as osmotic demyelination syndrome (ODS) during administration, follow the important administration instructions, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

HOW SUPPLIED

Potassium Chloride in Sodium Chloride Injection, USP in VIAFLEX Plus Plastic Container is available as follows:

Code	Size (mL)	NDC	Product Name
2B1357	1000	0338-0704-34	20 mEq/L Potassium Chloride in 0.45% Sodium Chloride Injection, USP
2B1764	1000	0338-0691-04	20 mEq/L Potassium Chloride in 0.9% Sodium Chloride Injection, USP
2B1984	1000	0338-0695-04	40 mEq/L Potassium Chloride in 0.9% Sodium Chloride Injection, USP

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored between 20ºC to 25°C (68º F to 77°F). [See USP controlled room temperature.]; brief exposure up to 40° C (104° F) does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLUS PLASTIC CONTAINER

For information on risk of air embolism – see PRECAUTIONS.

To Open

Tear overwrap down side at slit 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. Remove plastic 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.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

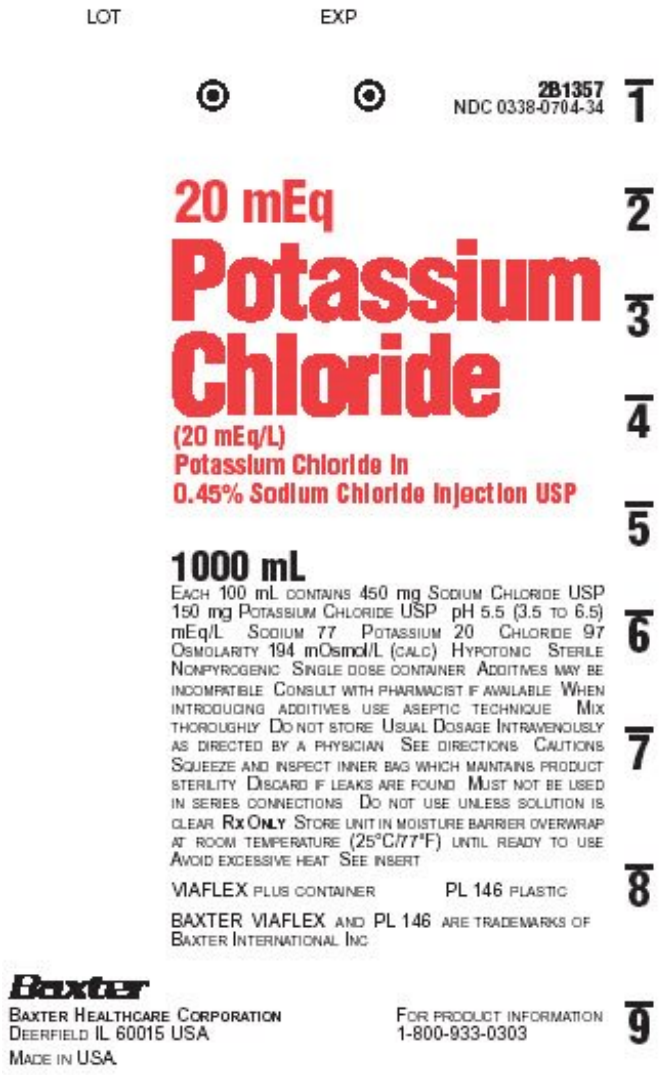
Printed in USA

07-19-78-210

Rev. January 2019

For Product Information
1-800-933-0303

PACKAGE LABELING - PRINCIPLE DISPLAY PANEL



Container Label

Container Label

LOT EXP

2B1357
NDC 0338-0704-34

20 mEq
Potassium Chloride
(20 mEq/L)
Potassium Chloride in
0.45% Sodium Chloride Injection USP

1000 mL

EACH 100 mL CONTAINS 450 mg SODIUM CHLORIDE USP
150 mg POTASSIUM CHLORIDE USP pH 5.5 (3.5 TO 6.5)
mEq/L SODIUM 77 POTASSIUM 20 CHLORIDE 97

OSMOLARITY 194 mOsmol/L (CALC) HYPOTONIC STERILE
NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE
INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE WHEN

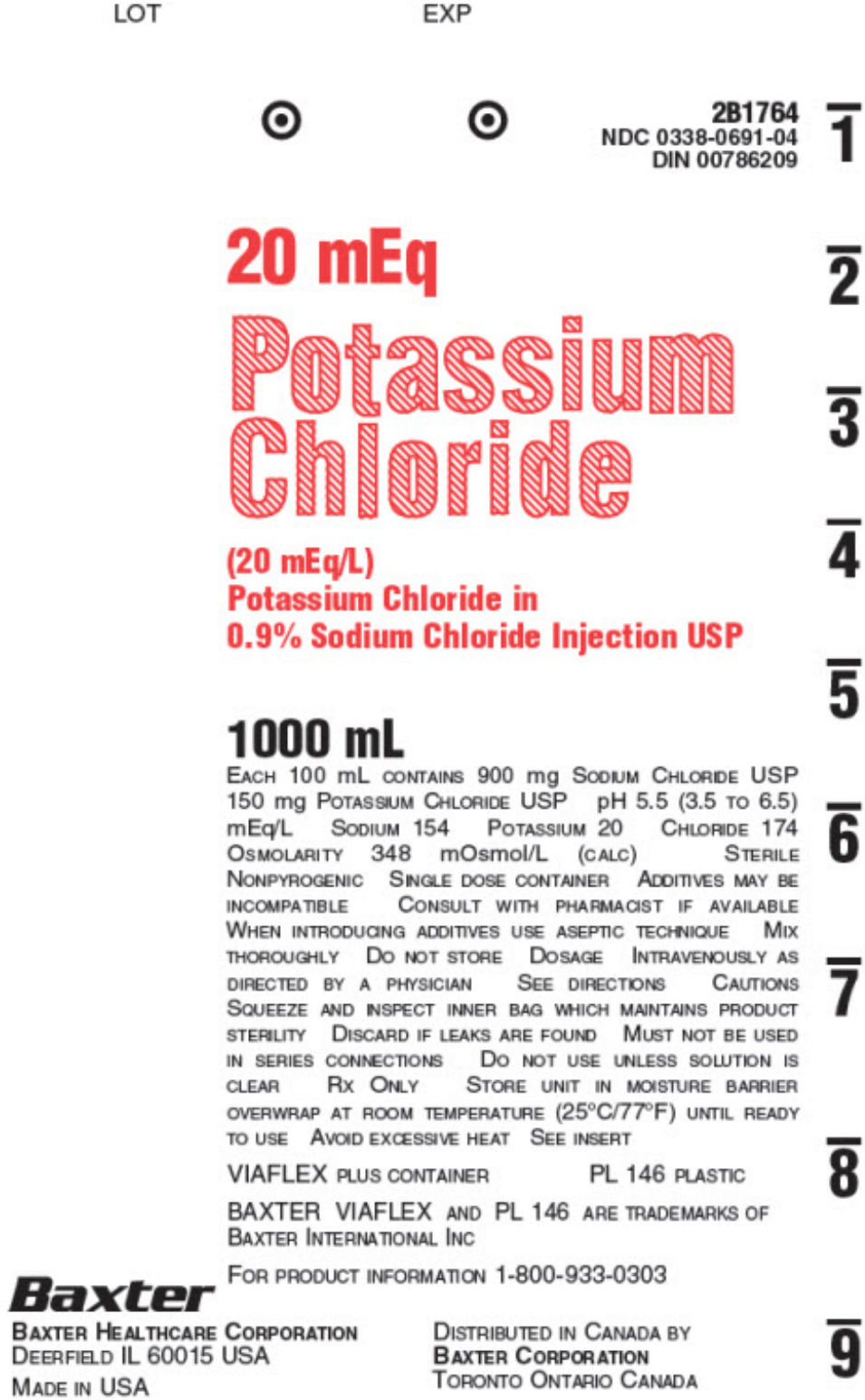
INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE USUAL DOSAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR **RX ONLY** STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT

VIAFLEX PLUS CONTAINER PL 146 PLASTIC

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA

FOR PRODUCT INFORMATION
1-800-933-0303



Container Label

LOT EXP

2B1764
NDC 0338-0691-04
DIN 00786209

1000 mL

EACH 100 mL CONTAINS 900 mg SODIUM CHLORIDE USP
150 mg POTASSIUM CHLORIDE USP pH 5.5 (3.5 TO 6.5)
mEq/L SODIUM 154 POTASSIUM 20 CHLORIDE 174
OSMOLARITY 348 mOsmol/L (CALC) STERILE
NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE
INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE
WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX
THOROUGHLY DO NOT STORE 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 **RX ONLY** STORE UNIT IN MOISTURE BARRIER
OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY
TO USE AVOID EXCESSIVE HEAT SEE INSERT

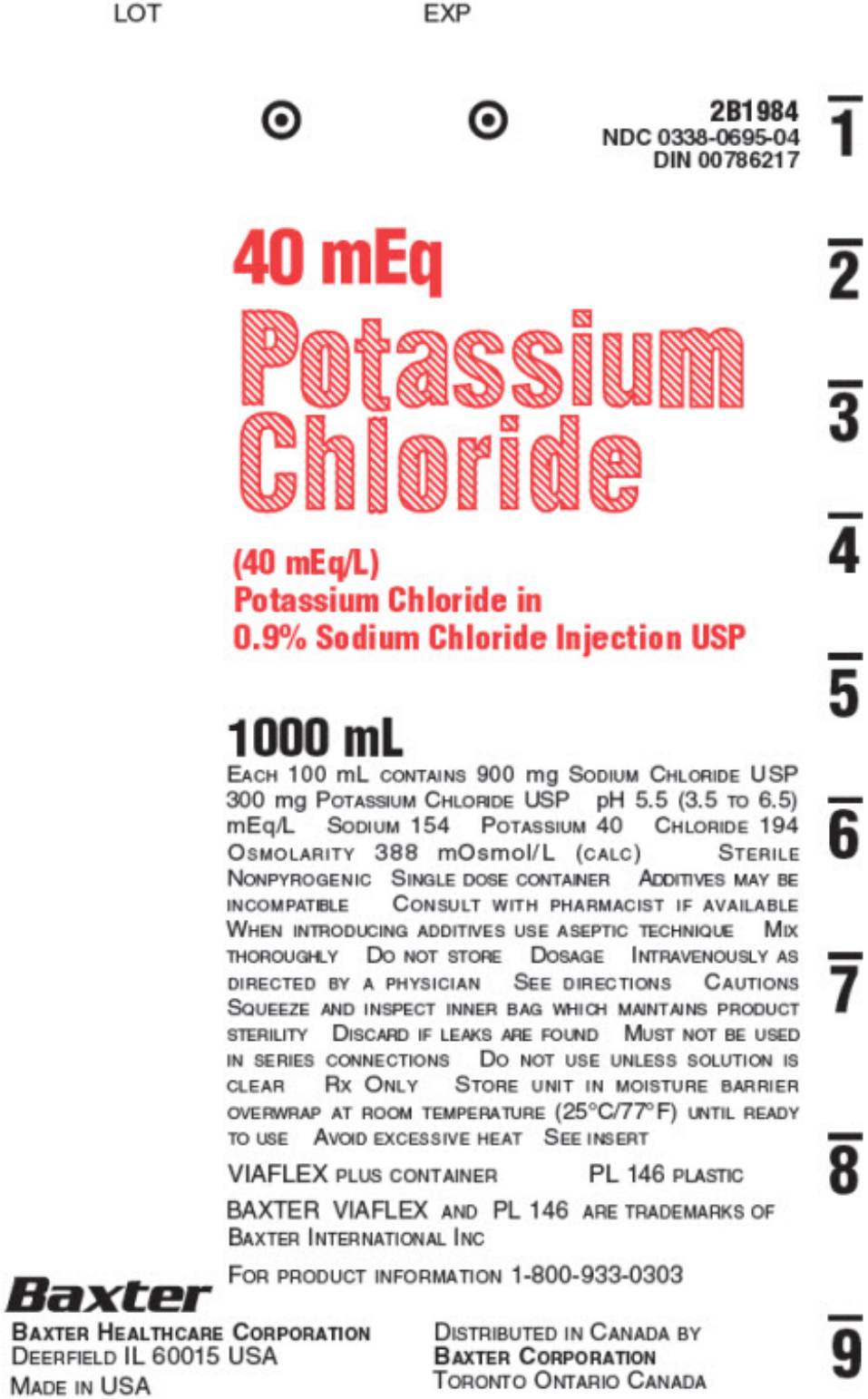
VIAFLEX PLUS CONTAINER PL 146 PLASTIC
BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF
BAXTER INTERNATIONAL INC

FOR PRODUCT INFORMATION 1-800-933-0303

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

DISTRIBUTED IN CANADA BY
BAXTER CORPORATION
TORONTO ONTARIO CANADA



Container Label

LOT EXP

2B1984
NDC 0338-0695-04
DIN 00786217

1000 mL

EACH 100 mL CONTAINS 900 mg SODIUM CHLORIDE USP
300 mg POTASSIUM CHLORIDE USP pH 5.5 (3.5 TO 6.5)
mEq/L SODIUM 154 POTASSIUM 40 CHLORIDE 194
OSMOLARITY 388 mOsmol/L (CALC) STERILE
NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE
INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE
WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX
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FOR PRODUCT INFORMATION 1-800-933-0303

Baxter

BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

DISTRIBUTED IN CANADA BY
BAXTER CORPORATION

TORONTO ONTARIO CANADA

POTASSIUM CHLORIDE IN SODIUM CHLORIDE

potassium chloride and sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0695
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	900 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	300 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0695-04	14 in 1 CARTON	02/02/1979	
1		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
NDA	NDA017648	02/02/1979	

POTASSIUM CHLORIDE IN SODIUM CHLORIDE

potassium chloride and sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0691
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	900 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	150 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0691-04	14 in 1 CARTON	02/02/1979	
1		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
NDA	NDA017648	02/02/1979	

POTASSIUM CHLORIDE IN SODIUM CHLORIDE

potassium chloride and sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0704
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	450 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	150 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0704-34	14 in 1 CARTON	02/02/1979	
1		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
NDA	NDA017648	02/02/1979	

Labeler - Baxter Healthcare Company (005083209)

Establishment

Name	Address	ID/FEI	Business Operations

Baxter Healthcare Corporation		059140764	MANUFACTURE(0338-0695, 0338-0691, 0338-0704) , ANALYSIS(0338-0695, 0338-0691, 0338-0704) , LABEL(0338-0695, 0338-0691, 0338-0704) , PACK(0338-0695, 0338-0691, 0338-0704) , STERILIZE(0338-0695, 0338-0691, 0338-0704)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0695, 0338-0691, 0338-0704)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		189326168	ANALYSIS(0338-0695, 0338-0691, 0338-0704) , LABEL(0338-0695, 0338-0691, 0338-0704) , MANUFACTURE(0338-0695, 0338-0691, 0338-0704) , PACK(0338-0695, 0338-0691, 0338-0704) , STERILIZE(0338-0695, 0338-0691, 0338-0704)

Revised: 1/2019

Baxter Healthcare Company