

POTASSIUM CHLORIDE - potassium chloride injection, solution, concentrate

Fresenius Kabi USA, LLC

Potassium Chloride for Injection Concentrate USP

Rx only

Concentrate Must Be Diluted Before Use

FOR INTRAVENOUS INFUSION ONLY

MUST BE DILUTED PRIOR TO INJECTION

DESCRIPTION:

Potassium Chloride for Injection Concentrate, USP is a sterile, nonpyrogenic concentrated solution of Potassium Chloride, USP in Water for Injection to be administered by intravenous infusion only after dilution in a larger volume of fluid.

Each mL of Potassium Chloride for Injection Concentrate contains 2 mEq of K⁺ and Cl⁻ equivalent to 149 mg of potassium chloride and has an osmolarity of 4000 mOsmol/L (calc). A more concentrated Potassium Chloride for Injection Concentrate is also available. Each mL of this injection contains 3 mEq of K⁺ and Cl⁻ equivalent to 224 mg of potassium chloride and has an osmolarity of 6000 mOsmol/L(calc).

pH (4.0-8.0) may have been adjusted with hydrochloric acid and if necessary, potassium hydroxide.

Some packages are intended for multiple dose use and contain preservatives (0.05% methylparaben and 0.005% propylparaben). A summary of the available products is presented in the **HOW SUPPLIED** section.

Potassium Chloride for Injection Concentrate (appropriately diluted) is a parenteral fluid and electrolyte replenisher.

CLINICAL PHARMACOLOGY:

Potassium is the chief cation of body cells (160 mEq/L of intracellular water) and is concerned with the maintenance of body fluid composition and electrolyte balance. Potassium participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart. 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.

Normally about 80 to 90% of the potassium intake is excreted in the urine, the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well, so that during fasting, or in patients on a potassium-free diet,

potassium loss from the body continues resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

INDICATIONS AND USAGE:

Potassium Chloride for Injection Concentrate, USP is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.

CONTRAINDICATIONS:

Potassium Chloride for Injection Concentrate is contraindicated in diseases where high potassium levels may be encountered, and in patients with hyperkalemia, renal failure and in conditions in which potassium retention is present.

WARNINGS:

Potentially Fatal Cardiac Adverse Reactions with Undiluted Intravenous Administration

Direct patient injection of potassium chloride at this concentration may be instantaneously fatal. Potassium Chloride for Injection Concentrate must be diluted before administration. Fatal cardiac arrhythmia and cardiac arrest have occurred when potassium chloride was administered in an undiluted form.

To avoid potassium intoxication, do not infuse these solutions rapidly. In patients with renal insufficiency, administration of potassium chloride may cause potassium intoxication and life-threatening hyperkalemia.

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

In patients with diminished renal function, administration of solutions containing potassium ions may result in potassium retention.

This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum. Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

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. Significant deviations from normal concentrations may require the use of additional electrolyte supplements, or the use of electrolyte-free dextrose solutions to which individualized electrolyte supplements may be added.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac disease, particularly in the presence of renal disease, and in such instances, cardiac monitoring is recommended.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.

If the administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

Pregnancy

Teratogenic Effects: Pregnancy Category C — Animal reproduction studies have not been conducted with potassium chloride. It is also not known whether potassium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium chloride should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS:

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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, hypervolemia, and hyperkalemia.

Too rapid infusion of hypertonic solutions may cause local pain and, rarely, vein irritation. Rate of administration should be adjusted according to tolerance.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

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:

In the event of fluid overload during parenteral therapy, reevaluate the patient's condition, and institute appropriate corrective treatment.

In the event of overdosage with potassium-containing solutions, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:

1. Dextrose Injection, USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL/hour.
2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
3. Hemodialysis and peritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

DOSAGE AND ADMINISTRATION:

Potassium Chloride for Injection Concentrate must be diluted before administration.

Care must be taken to ensure there is complete mixing of the potassium chloride with the large volume fluid, particularly if soft or bag type containers are used.

The dose and rate of administration are dependent upon the specific condition of each patient.

If the serum potassium level is greater than 2.5 mEq/L, potassium can be given at a rate not to exceed 10 mEq/hour and in a concentration of up to 40 mEq/L. The 24 hour total dose should not exceed 200 mEq.

If urgent treatment is indicated (serum potassium level less than 2 mEq/L and electrocardiographic changes and/or muscle paralysis), potassium chloride may be infused very cautiously at a rate of up to 40 mEq/hour. In such cases, continuous cardiac monitoring is essential. As much as 400 mEq may be administered in a 24 hour period. In critical conditions, potassium chloride may be administered in saline (unless contraindicated) rather than in dextrose containing fluids, as dextrose may lower serum potassium levels.

Prior to entering a vial, cleanse the rubber closure with a suitable antiseptic agent.

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

HOW SUPPLIED:

The following are packaged in plastic vials.

Product Code	Unit of Sale	Total Potassium Ion	Potassium Chloride per mL	Each
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96505	NDC 63323-965-05 Unit of 25	10 mEq (0.39 g)	149 mg	NDC 63323-965-01 5 mL in a 10 mL Single Dose Vial
96510	NDC 63323-965-10 Unit of 25	20 mEq (0.78 g)	149 mg	NDC 63323-965-03 10 mL Single Dose Vial
96520	NDC 63323-965-20 Unit of 25	40 mEq (1.56 g)	149 mg	NDC 63323-965-02 20 mL Single Dose Vial

These are Single Dose Vials, no preservative added, packaged 25 vials per tray. Unused portion of vial should be discarded.

Product Code	Unit of Sale	Total Potassium Ion	Potassium Chloride per mL	Each
96730	NDC 63323-967-30 Unit of 25	60 mEq (2.35 g)	149 mg	NDC 63323-967-01 30 mL Multiple Dose Vial

This is a Multiple Dose Vial, preserved with 0.05% methylparaben and 0.005% propylparaben, packaged 25 vials per tray.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Use only if solution is clear, seal intact and undamaged.

Vial stoppers do not contain natural rubber latex.



Lake Zurich, IL 60047
www.fresenius-kabi.com/us
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Revised: February 2023

PACKAGE LABEL - PRINCIPAL DISPLAY - Potassium Chloride 5 mL Single

Dose Vial Label

NDC 63323-965-01 96505

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

10 mEq per 5 mL (2 mEq per mL)

5 mL Single Dose Vial Rx only

NDC 63323-965-01 96505		Preservative Free	
POTASSIUM CHLORIDE <i>For Injection Concentrate, USP</i>		MUST BE DILUTED PRIOR TO IV ADMINISTRATION Sterile, Nonpyrogenic Each mL contains: Potassium chloride 2 mEq (149 mg); Water for Injection q.s. HCl and/or KOH may have been added for pH adjustment. 4000 mOsmol/L (calc.) Contains no more than 100 mcg/L of aluminum. Usual dosage: See insert. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Vial stoppers do not contain natural rubber latex.	www.fresenius-kabi.com/us
Concentrate Must Be Diluted Before Use			
10 mEq per 5 mL (2 mEq per mL)			
5 mL Single Dose Vial Rx only			
			3 63323-965-01 3
			401699K
			LOT/EXP

PACKAGE LABEL - PRINCIPAL DISPLAY - Potassium Chloride 5 mL Single Dose Vial Tray Label

NDC 63323-965-05 96505

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

10 mEq per 5 mL (2 mEq per mL)

Rx only

25 x 5 mL Single Dose Vials

NDC 63323-965-05 96505		Preservative Free	
POTASSIUM CHLORIDE <i>For Injection Concentrate, USP</i>		MUST BE DILUTED PRIOR TO IV ADMINISTRATION Sterile, Nonpyrogenic Each mL contains: Potassium chloride 2 mEq (149 mg); Water for Injection q.s. HCl and/or KOH may have been added for pH adjustment. 4000 mOsmol/L (calc.) Contains no more than 100 mcg/L of aluminum. Usual dosage: See insert. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Vial stoppers do not contain natural rubber latex.	www.fresenius-kabi.com/us
Concentrate Must Be Diluted Before Use			
10 mEq per 5 mL (2 mEq per mL)			
25 x 5 mL Single Dose Vials Rx only			
		4 2 4 4 5 A	
			(01)20363323965055

PACKAGE LABEL - PRINCIPAL DISPLAY - Potassium Chloride 10 mL Single Dose Vial Label

NDC 63323-965-03 96510

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

20 mEq per 10 mL

(2 mEq per mL)

10 mL Single Dose Vial Rx only

NDC 63323-965-03 96510

POTASSIUM CHLORIDE
For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

20 mEq per 10 mL
(2 mEq per mL) Rx only

10 mL Single Dose Vial

MUST BE DILUTED PRIOR TO IV ADMINISTRATION

Sterile, Nonpyrogenic

Each mL contains: Potassium chloride 2 mEq (149 mg); Water for Injection q.s. HCl and/or KOH may have been added for pH adjustment.

4000 mOsmol/L (calc.)

Contains no more than 100 mcg/L of aluminum.

Usual Dosage: See insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Vial stoppers do not contain natural rubber latex.

Preservative Free

www.fresenius-kabi.com/us



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LOT/EXP

PACKAGE LABEL - PRINCIPAL DISPLAY - Potassium Chloride 10 mL Tray Label

NDC 63323-965-10 96510

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

20 mEq per 10 mL

(2 mEq per mL)

25 x 10 mL Single Dose Vials Rx only

NDC 63323-965-10 96510

POTASSIUM CHLORIDE
For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

20 mEq per 10 mL
(2 mEq per mL) Rx only

25 x 10 mL Single Dose Vials

MUST BE DILUTED PRIOR TO IV ADMINISTRATION

Sterile, Nonpyrogenic

Each mL contains: Potassium chloride 2 mEq (149 mg); Water for Injection q.s. HCl and/or KOH may have been added for pH adjustment.

4000 mOsmol/L (calc.)

Contains no more than 100 mcg/L of aluminum.

Usual Dosage: See insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Vial stoppers do not contain natural rubber latex.

Preservative Free

www.fresenius-kabi.com/us



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(01)20363323965109

PACKAGE LABEL - PRINCIPAL DISPLAY - Potassium Chloride 20 mL Single Dose Vial Label

NDC 63323-965-02 96520

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

40 mEq per 20 mL

(2 mEq per mL)

20 mL Single Dose Vial Rx only

NDC 63323-965-02 96520		Preservative Free	
POTASSIUM CHLORIDE			
<i>For Injection Concentrate, USP</i>			
Concentrate Must Be Diluted Before Use			
40 mEq per 20 mL			
(2 mEq per mL)			
20 mL Single Dose Vial Rx only			
		MUST BE DILUTED PRIOR TO IV ADMINISTRATION	
		Sterile, Nonpyrogenic	
		Each mL contains:	
		Potassium chloride 2 mEq (149 mg);	
		Water for Injection q.s. HCl and/or	
		KOH may have been added for	
		pH adjustment.	
		4000 mOsmol/L (calc.)	
		Contains no more than 100 mcg/L of aluminum.	
		Usual Dosage: See insert.	
		Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].	
		Vial stoppers do not contain natural rubber latex.	
		Fresenius Kabi Lake Zurich, IL 60047	
			
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		LOT/EXP	

PACKAGE LABEL - PRINCIPAL DISPLAY - Potassium Chloride 20 mL Tray Label

NDC 63323-965-20 96520

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

40 mEq per 20 mL

(2 mEq per mL)

25 x 20 mL Single Dose Vials Rx only

NDC 63323-965-20

96520

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

40 mEq per 20 mL

(2 mEq per mL)

25 x 20 mL

Rx only

Single Dose Vials

Preservative Free

MUST BE DILUTED PRIOR TO IV ADMINISTRATION

Sterile, Nonpyrogenic

Each mL contains: Potassium chloride 2 mEq (149 mg); Water for Injection q.s. HCl and/or KOH may have been added for pH adjustment.

4000 mOsmol/L (calc.)

Contains no more than 100 mcg/L of aluminum.

Usual Dosage: See insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Vial stoppers do not contain natural rubber latex.

Fresenius Kabi Lake Zurich, IL 60047

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(01)20363323965208

PACKAGE LABEL - PRINCIPAL DISPLAY - Potassium Chloride 30 mL Multiple Dose Vial Label

NDC 63323-967-01 96730

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

60 mEq per 30 mL(2 mEq per mL)

30 mL Multiple Dose Vial Rx only

NDC 63323-967-01

96730

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

60 mEq per 30 mL

(2 mEq per mL)

30 mL Multiple Dose Vial

Rx only

MUST BE DILUTED PRIOR TO IV ADMINISTRATION

Sterile, Nonpyrogenic

Each mL contains: Potassium chloride 2 mEq (149 mg); methylparaben 0.05%; propylparaben 0.005%; Water for Injection q.s. HCl and/or KOH may have been added for pH adjustment.

4000 mOsmol/L (calc.)

Contains no more than 100 mcg/L of aluminum.

Usual Dosage: See insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Vial stoppers do not contain natural rubber latex.

Fresenius Kabi Lake Zurich, IL 60047

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LOT/EXP

PACKAGE LABEL - PRINCIPAL DISPLAY - Potassium Chloride 30 mL Multiple Dose Vial Tray Label

NDC 63323-967-30 96730

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

60 mEq per 30 mL (2 mEq per mL)
Rx only
25 x 30 mL Multiple Dose Vials

NDC 63323-967-3096730

POTASSIUM CHLORIDE

For Injection Concentrate, USP

Concentrate Must Be Diluted Before Use

60 mEq per 30 mL

(2 mEq per mL)

25 x 30 mL

Rx onlyMultiple Dose Vials

MUST BE DILUTED PRIOR TO IV ADMINISTRATION

Sterile, Nonpyrogenic

Each mL contains: Potassium chloride 2 mEq (149 mg); methylparaben 0.05%; propylparaben 0.005%; Water for Injection q.s. HCl and/or KOH may have been added for pH adjustment.

4000 mOsmol/L (calc.)

Contains no more than 100 mcg/L of aluminum.


Usual Dosage: See insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Vial stoppers do not contain natural rubber latex.

Fresenius Kabi Lake Zurich, IL 60047

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(01)20363323967301

POTASSIUM CHLORIDE

potassium chloride injection, solution, concentrate

Product Information						
Product Type	HUMAN PRESCRIPTION DRUG		Item Code (Source)	NDC:63323-965		
Route of Administration	INTRAVENOUS					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Strength	Strength		
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)			POTASSIUM CATION	2 meq in 1 mL		
Inactive Ingredients						
Ingredient Name				Strength		
HYDROCHLORIC ACID (UNII: QTT17582CB)						
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)						
WATER (UNII: 059QF0KO0R)						
Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:63323					

1	NDC:63323-965-05	25 in 1 TRAY	09/27/1999	
1	NDC:63323-965-01	5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:63323-965-10	25 in 1 TRAY	09/27/1999	
2	NDC:63323-965-03	10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
3	NDC:63323-965-20	25 in 1 TRAY	09/27/1999	
3	NDC:63323-965-02	20 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088901	09/27/1999	

POTASSIUM CHLORIDE

potassium chloride injection, solution, concentrate

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63323-967
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	2 meq in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63323-967-30	25 in 1 TRAY	09/05/2000	
1	NDC:63323-	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a		

967-01	Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088908	09/05/2000	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment			
Name	Address	ID/FEI	Business Operations
Fresenius Kabi USA, LLC		840771732	MANUFACTURE(63323-965, 63323-967) , ANALYSIS(63323-965, 63323-967)