

# POTASSIUM CHLORIDE- potassium chloride powder, for solution

## Advagen Pharma Limited

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### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use POTASSIUM CHLORIDE safely and effectively. See full prescribing information for POTASSIUM CHLORIDE.

### POTASSIUM CHLORIDE for oral solution

#### Initial U.S. Approval: 1948

#### INDICATIONS AND USAGE

Potassium Chloride is a potassium salt indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient. ( 1)

#### DOSAGE AND ADMINISTRATION

Dilute prior to administration. ( 2.1, 5.1)

Monitor serum potassium and adjust dosage accordingly ( 2.2, 2.3)

If serum potassium concentration is <2.5 mEq/L, use intravenous potassium instead of oral supplementation ( 2.1)

#### *Treatment of hypokalemia:*

- Adults: Initial doses range from 40-100 mEq/day in 2-5 divided doses: limit doses to 40 mEq per dose. Total daily dose should not exceed 200 mEq ( 2.2)
- Pediatric patients aged birth to 16 years old: 2-4 mEq/kg/day in divided doses; not to exceed 1 mEq/kg as a single dose or 40 mEq whichever is lower; if deficits are severe or ongoing losses are great, consider intravenous therapy. Total daily dose should not exceed 100 mEq ( 2.3)

#### *Maintenance or Prophylaxis of hypokalemia:*

- Adults: Typical dose is 20 mEq per day ( 2.2)
- Pediatric patients aged birth to 16 years old: typical dose is 1 mEq/kg/day. Do not to exceed 3 mEq/kg/day ( 2.3)

#### DOSAGE FORMS AND STRENGTHS

- Potassium Chloride for Oral Solution, USP 20 mEq: Each pouch contains 1.5 g of Potassium Chloride providing potassium 20 mEq and chloride 20 mEq. ( 3)

#### CONTRAINDICATIONS

- Concomitant use with potassium sparing diuretics. ( 4)

-----**WARNINGS AND PRECAUTIONS**-----

- Gastrointestinal Irritation: Dilute before use, take with meals ( 5.1)

-----**ADVERSE REACTIONS**-----

Most common adverse reactions are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea. ( 6)

**To report SUSPECTED ADVERSE REACTIONS, contact Advagen Pharma Ltd, at 888-413-0949 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

-----**DRUG INTERACTIONS**-----

- Potassium sparing diuretics: Avoid concomitant use ( 7.1)
- Renin-angiotensin-aldosterone inhibitors: Monitor for hyperkalemia ( 7.2)
- Nonsteroidal Anti-Inflammatory drugs: Monitor for hyperkalemia ( 7.3)

-----**USE IN SPECIFIC POPULATIONS**-----

Cirrhosis: Initiate therapy at the low end of the dosing range ( 8.6)  
Renal Impairment: Initiate therapy at the low end of the dosing range ( 8.7)

**Revised: 3/2023**

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**FULL PRESCRIBING INFORMATION: CONTENTS\***

**1 INDICATIONS AND USAGE**

**2 DOSAGE AND ADMINISTRATION**

- 2.1 Administration and Monitoring
- 2.2 Adult Dosing
- 2.3 Pediatric Dosing

**3 DOSAGE FORMS AND STRENGTHS**

**4 CONTRAINDICATIONS**

**5 WARNINGS AND PRECAUTIONS**

- 5.1 Gastrointestinal Irritation

**6 ADVERSE REACTIONS**

**7 DRUG INTERACTIONS**

- 7.1 Potassium-Sparing Diuretics
- 7.2 Renin-Angiotensin-Aldosterone System Inhibitors
- 7.3 Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

**8 USE IN SPECIFIC POPULATIONS**

- 8.1 Pregnancy
- 8.2 Lactation
- 8.4 Pediatric Use
- 8.5 Geriatric Use
- 8.6 Cirrhotics
- 8.7 Renal Impairment

**10 OVERDOSAGE**

- 10.1 Symptoms
- 10.2 Treatment

**11 DESCRIPTION**

**12 CLINICAL PHARMACOLOGY**

- 12.1 Mechanism of Action
- 12.3 Pharmacokinetics

**16 HOW SUPPLIED/STORAGE AND HANDLING**

\* Sections or subsections omitted from the full prescribing information are not listed.

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

Potassium Chloride is indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.

### **2 DOSAGE AND ADMINISTRATION**

#### **2.1 Administration and Monitoring**

##### *Monitoring*

Monitor serum potassium and adjust dosages accordingly. For treatment of hypokalemia, monitor potassium levels daily or more often depending on the severity of hypokalemia until they return to normal. Monitor potassium levels monthly to biannually for maintenance or prophylaxis.

The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance, volume status, electrolytes, including magnesium, sodium, chloride, phosphate, and calcium, electrocardiograms and the clinical status of the patient. Correct volume status, acid-base balance and electrolyte deficits as appropriate.

##### *Administration*

Dilute the contents of 1 pouch of potassium chloride for oral solution in at least 4 ounces of cold water [see *Warnings and Precautions (5.1)*].

Take with meals or immediately after eating.

If serum potassium concentration is  $<2.5$  mEq/L, use intravenous potassium instead of oral supplementation.

#### **2.2 Adult Dosing**

##### *Treatment of hypokalemia:*

Daily dose range from 40 to 100 mEq. Give in 2 to 5 divided doses: limit doses to 40 mEq per dose. The total daily dose should not exceed 200 mEq in a 24 hour period.

##### *Maintenance or Prophylaxis*

Typical dose is 20 mEq per day. Individualize dose based upon serum potassium levels.

Studies support the use of potassium replacement in digitalis toxicity. When alkalosis is present, normokalemia and hyperkalemia may obscure a total potassium deficit. The advisability of use of potassium replacement in the setting of hyperkalemia is uncertain.

## **2.3 Pediatric Dosing**

### *Treatment of hypokalemia:*

Pediatric patients aged birth to 16 years old: The initial dose is 2 to 4 mEq/kg/day in divided doses; do not exceed as a single dose 1 mEq/kg or 40 mEq, whichever is lower; maximum daily doses should not exceed 100 mEq. If deficits are severe or ongoing losses are great, consider intravenous therapy.

### *Maintenance or Prophylaxis*

Pediatric patients aged birth to 16 years old: Typical dose is 1 mEq/kg/day. Do not exceed 3 mEq/kg/day.

## **3 DOSAGE FORMS AND STRENGTHS**

Each pouch contains 1.5 g of potassium chloride supplying 20 mEq of potassium and 20 mEq of chloride.

## **4 CONTRAINDICATIONS**

Potassium chloride is contraindicated in patients on potassium sparing diuretics.

## **5 WARNINGS AND PRECAUTIONS**

### **5.1 Gastrointestinal Irritation**

May cause gastrointestinal irritation. Increased dilution of the solution and taking with meals may reduce gastrointestinal irritation [see *Dosage and Administration (2.1)*].

## **6 ADVERSE REACTIONS**

The most common adverse reactions to oral potassium salts are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea.

## **7 DRUG INTERACTIONS**

### **7.1 Potassium-Sparing Diuretics**

Use with potassium-sparing diuretics can produce severe hyperkalemia. Avoid concomitant use.

### **7.2 Renin-Angiotensin-Aldosterone System Inhibitors**

Drugs that inhibit the renin-angiotensin-aldosterone system (RAAS) including angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), spironolactone, eplerenone, or aliskiren produce potassium retention by inhibiting aldosterone production. Closely monitor potassium in patients receiving concomitant RAAS therapy.

### **7.3 Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)**

NSAIDs may produce potassium retention by reducing renal synthesis of prostaglandin E and impairing the renin-angiotensin system. Closely monitor potassium in patients on concomitant NSAIDs.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

There are no human data related to use of Potassium Chloride during pregnancy, and animal studies have not been conducted. Potassium supplementation that does not lead to hyperkalemia is not expected to cause fetal harm.

The background risk for major birth defects and miscarriage in the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

### **8.2 Lactation**

#### Risk Summary

The normal potassium ion content of human milk is about 13 mEq per liter. Since potassium from oral supplements such as Potassium Chloride becomes part of the body potassium pool, as long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

### **8.4 Pediatric Use**

Clinical trial data from published literature have demonstrated the safety and effectiveness of potassium chloride in children with diarrhea and malnutrition from birth to 16 years.

### **8.5 Geriatric Use**

Clinical studies of Potassium Chloride 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.

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.

### **8.6 Cirrhotics**

Patients with cirrhosis should usually be started at the low end of the dosing range, and the serum potassium level should be monitored frequently. [see *Clinical Pharmacology (12.3)*].

## **8.7 Renal Impairment**

Patients with renal impairment have reduced urinary excretion of potassium and are at substantially increased risk of hyperkalemia. Patients with impaired renal function, particularly if the patient is on ACE inhibitors, ARBs, or nonsteroidal anti-inflammatory drugs should usually be started at the low end of the dosing range because of the potential for development of hyperkalemia. The serum potassium level should be monitored frequently. Renal function should be assessed periodically.

## **10 OVERDOSAGE**

### **10.1 Symptoms**

The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly potentially fatal hyperkalemia can result.

Hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration (6.5–8.0 mEq/L) and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest (9–12 mEq/L).

### **10.2 Treatment**

Treatment measures for hyperkalemia include the following:

1. Monitor closely for arrhythmias and electrolyte changes.
2. Eliminate foods and medications containing potassium and of any agents with potassium-sparing properties such as potassium-sparing diuretics, ARBS, ACE inhibitors, NSAIDS, certain nutritional supplements and many others.
3. Administer intravenous calcium gluconate if the patient is at no risk or low risk of developing digitalis toxicity.
4. Administer intravenously 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1000 mL.
5. Correct acidosis, if present, with intravenous sodium bicarbonate.
6. Use exchange resins, hemodialysis, or peritoneal dialysis.

In patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

## **11 DESCRIPTION**

Potassium Chloride is a white crystalline or colorless solid. It is soluble in water and slightly soluble in alcohol. Chemically, Potassium Chloride is K-Cl with a molecular mass of 74.55.

Each pouch of light pink to orange powder contains 1.5 g of potassium chloride, USP, which is equivalent to potassium 20 mEq and chloride 20 mEq and the following inactive ingredients: citric acid anhydrous, colloidal silicon dioxide, FD&C Yellow #6 and sucralose.

## **12 CLINICAL PHARMACOLOGY**

### **12.1 Mechanism of Action**

The potassium ion ( $K^+$ ) is the principal intracellular cation of most body tissues. Potassium ions participate in a number of essential physiological processes including the maintenance of intracellular tonicity; the transmission of nerve impulses; the contraction of cardiac, skeletal, and smooth muscle; and the maintenance of normal renal function.

The intracellular concentration of potassium is approximately 150 to 160 mEq per liter. The normal adult plasma concentration is 3.5 to 5 mEq per liter. An active ion transport system maintains this gradient across the plasma membrane.

Potassium is a normal dietary constituent, and under steady-state conditions the amount of potassium absorbed from the gastrointestinal tract is equal to the amount excreted in the urine. The usual dietary intake of potassium is 50 to 100 mEq per day.

### **12.3 Pharmacokinetics**

Based on published literature, the rate of absorption and urinary excretion of potassium from KCl oral solution were higher during the first few hours after dosing relative to modified release KCl products. The bioavailability of potassium, as measured by the cumulative urinary excretion of  $K^+$  over a 24 hour post dose period, is similar for KCl solution and modified release products.

#### Specific Populations

##### *Cirrhotics*

Based on published literature, the baseline corrected serum concentrations of potassium measured over 3 h after administration in cirrhotic subjects who received an oral potassium load rose to approximately twice that of normal subjects who received the same load.

## **16 HOW SUPPLIED/STORAGE AND HANDLING**

Potassium Chloride for Oral Solution, is a light pink to orange powder available in one strength as follows:

20 mEq

NDC# 72888-024-06 pouch. Each pouch contains 1.5 g of potassium chloride providing potassium 20 mEq and chloride 20 mEq

NDC# 72888-024-07 carton of 30 pouches

NDC# 72888-024-43 carton of 50 pouches

NDC# 72888-024-10 carton of 100 pouches

### **Storage**

Store at Controlled Room Temperature, 25°C (77°F); excursions are permitted to 15° - 30°C (59° - 86°F).

Dispense in a tight, light-resistant container as defined in the USP

PROTECT from LIGHT.

Rx only

Distributed by:

**Advagen Pharma Ltd**

666 Plainsboro Road

Suite 605

Plainsboro, NJ 08536, USA.

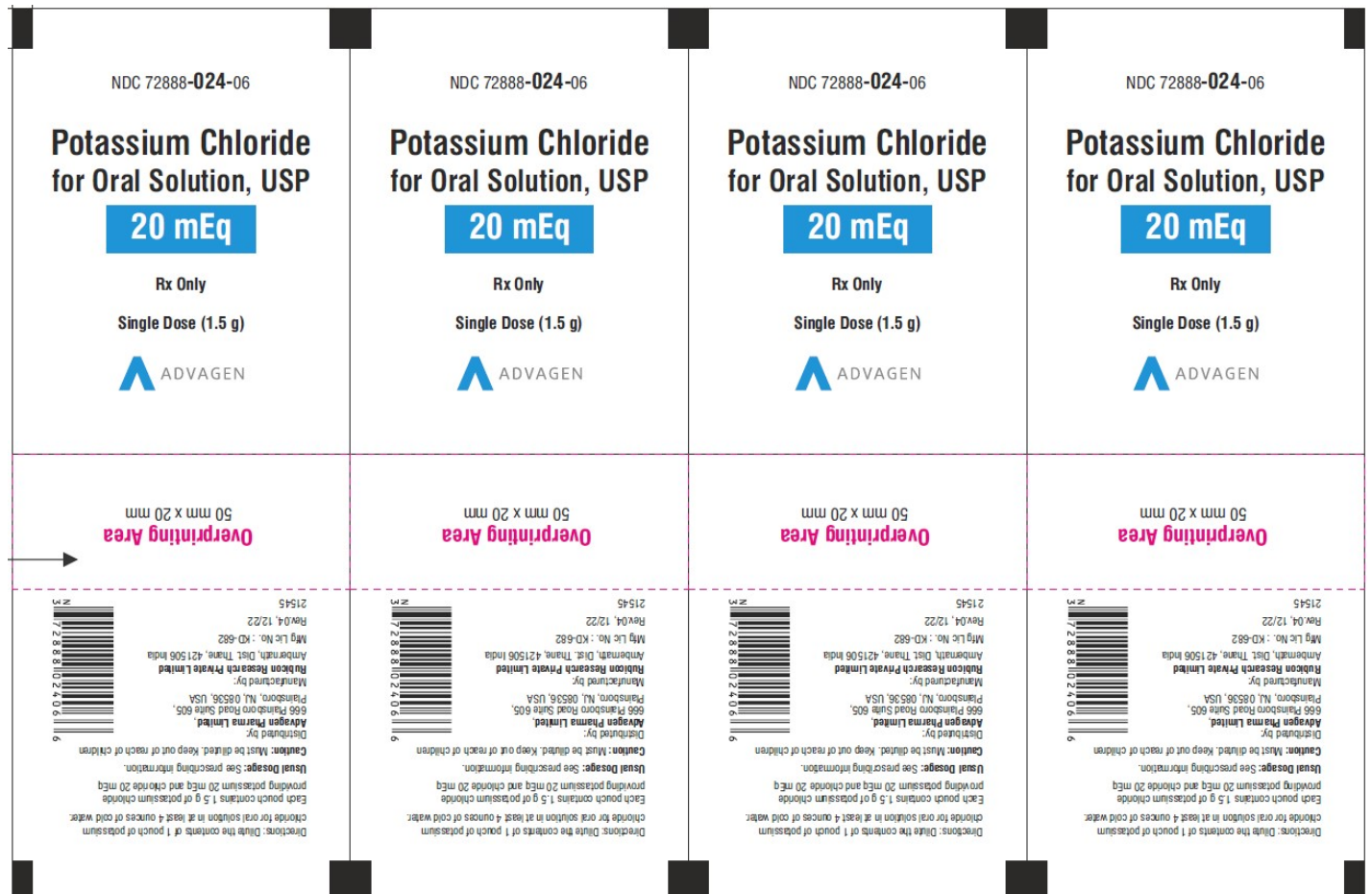
Manufactured by:

**Rubicon Research Private Limited**

Ambernath, Dist: Thane, 421506 India.

**Revised: 03/2023**






## PRINCIPAL DISPLAY PANEL - Potassium Chloride for Oral Solution, 20 mEq - 1.5 g Pouch Label - NDC 72888-024-06








## PRINCIPAL DISPLAY PANEL - Potassium Chloride for Oral Solution, 20 mEq -



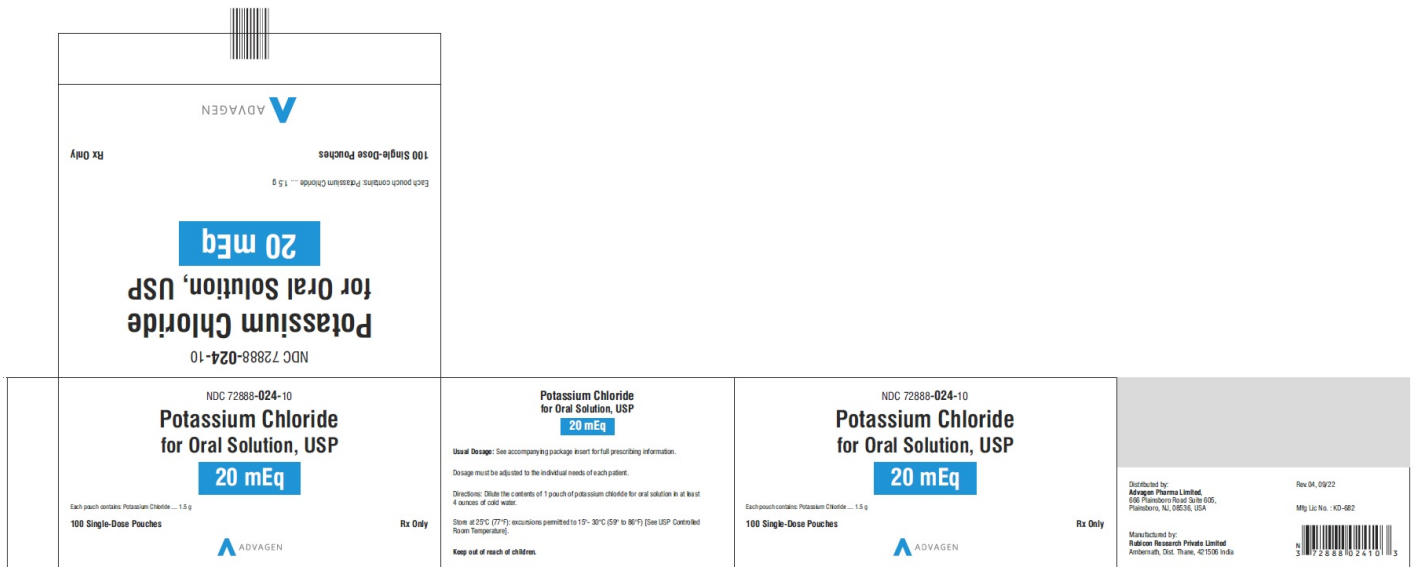
# NDC 72888-024-07 - 30s Pouch Label

			
<p style="text-align: center;">ADVAGEN </p> <p style="text-align: center;">Rx Only      30 Single-Dose Pouches</p> <p style="text-align: center;">Each pouch contains: Potassium Chloride ... 1.5 g</p> <p style="text-align: center;"><b>20 mEq</b></p> <p style="text-align: center;"><b>Potassium Chloride for Oral Solution, USP</b></p> <p style="text-align: center;">NDC 72888-024-07</p>			
<p style="text-align: center;">NDC 72888-024-07</p> <p style="text-align: center;"><b>Potassium Chloride for Oral Solution, USP</b></p> <p style="text-align: center;"><b>20 mEq</b></p> <p>Each pouch contains: Potassium Chloride ... 1.5 g</p> <p style="text-align: center;">30 Single-Dose Pouches</p> <p style="text-align: center;">Rx Only</p> <p style="text-align: center;">ADVAGEN </p>	<p style="text-align: center;"><b>Potassium Chloride for Oral Solution, USP</b></p> <p style="text-align: center;"><b>20 mEq</b></p> <p><b>Usual Dosage:</b> See accompanying package insert for full prescribing information.</p> <p>Dosage must be adjusted to the individual needs of each patient.</p> <p><b>Directions:</b> Dilute the contents of 1 pouch of potassium chloride for oral solution in at least 4 ounces of cold water.</p> <p>Store at 25°C (77°F); excursions permitted to 15°-30°C (59° to 86°F). [See USP Controlled Room Temperature].</p> <p><b>Keep out of reach of children.</b></p>	<p style="text-align: center;">NDC 72888-024-07</p> <p style="text-align: center;"><b>Potassium Chloride for Oral Solution, USP</b></p> <p style="text-align: center;"><b>20 mEq</b></p> <p>Each pouch contains: Potassium Chloride ... 1.5 g</p> <p style="text-align: center;">30 Single-Dose Pouches</p> <p style="text-align: center;">Rx Only</p> <p style="text-align: center;">ADVAGEN </p>	 <p style="text-align: center;">N 3 72888 102407 3</p> <p>Distributed by: <b>Advagen Pharma Limited</b>, 666 Plainsboro Road Suite 605, Plainsboro, NJ 08536, USA</p> <p>Manufactured by: <b>Rubicon Research Private Limited</b> Ambemath, Dist. Thane, 421506 India</p> <p>Mfg Lic No. : KD-682      Rev 04, 09/22</p>

# PRINCIPAL DISPLAY PANEL - Potassium Chloride for Oral Solution, 20 mEq - NDC 72888-024-43 - 50s Pouch Label

			
<p style="text-align: center;">ADVAGEN </p> <p style="text-align: center;">Rx Only      50 Single-Dose Pouches</p> <p style="text-align: center;">Each pouch contains: Potassium Chloride ... 1.5 g</p> <p style="text-align: center;"><b>20 mEq</b></p> <p style="text-align: center;"><b>Potassium Chloride for Oral Solution, USP</b></p> <p style="text-align: center;">NDC 72888-024-43</p>			
<p style="text-align: center;">NDC 72888-024-43</p> <p style="text-align: center;"><b>Potassium Chloride for Oral Solution, USP</b></p> <p style="text-align: center;"><b>20 mEq</b></p> <p>Each pouch contains: Potassium Chloride ... 1.5 g</p> <p style="text-align: center;">50 Single-Dose Pouches</p> <p style="text-align: center;">Rx Only</p> <p style="text-align: center;">ADVAGEN </p>	<p style="text-align: center;"><b>Potassium Chloride for Oral Solution, USP</b></p> <p style="text-align: center;"><b>20 mEq</b></p> <p><b>Usual Dosage:</b> See accompanying package insert for full prescribing information.</p> <p>Dosage must be adjusted to the individual needs of each patient.</p> <p><b>Directions:</b> Dilute the contents of 1 pouch of potassium chloride for oral solution in at least 4 ounces of cold water.</p> <p>Store at 25°C (77°F); excursions permitted to 15°-30°C (59° to 86°F). [See USP Controlled Room Temperature].</p> <p><b>Keep out of reach of children.</b></p>	<p style="text-align: center;">NDC 72888-024-43</p> <p style="text-align: center;"><b>Potassium Chloride for Oral Solution, USP</b></p> <p style="text-align: center;"><b>20 mEq</b></p> <p>Each pouch contains: Potassium Chloride ... 1.5 g</p> <p style="text-align: center;">50 Single-Dose Pouches</p> <p style="text-align: center;">Rx Only</p> <p style="text-align: center;">ADVAGEN </p>	 <p style="text-align: center;">N 3 72888 102443 1</p> <p>Distributed by: <b>Advagen Pharma Limited</b>, 666 Plainsboro Road Suite 605, Plainsboro, NJ 08536, USA</p> <p>Manufactured by: <b>Rubicon Research Private Limited</b> Ambemath, Dist. Thane, 421506 India</p> <p>Mfg Lic No. : KD-682      Rev 00, 09/22</p>

# PRINCIPAL DISPLAY PANEL - Potassium Chloride for Oral Solution, 20 mEq - NDC 72888-024-10 - 100s Pouch Label



# POTASSIUM CHLORIDE

potassium chloride powder, for solution

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:72888-024
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>POTASSIUM CHLORIDE</b> (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32Z N48698)	POTASSIUM CHLORIDE	1.5 g in 1.58 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	orange (light pink to orange)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72888-024-07	30 in 1 CARTON	03/24/2022	
1	NDC:72888-024-06	1.58 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:72888-024-43	50 in 1 CARTON	10/10/2022	
2	NDC:72888-024-06	1.58 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:72888-024-10	100 in 1 CARTON	03/24/2022	
3	NDC:72888-024-06	1.58 g in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214108	03/24/2022	

**Labeler** - Advagen Pharma Limited (051627256)

**Registrant** - Rubicon Research Private Limited (918629544)

## Establishment

Name	Address	ID/FEI	Business Operations
Rubicon Research Private Limited		677604197	manufacture(72888-024) , analysis(72888-024) , label(72888-024)

Revised: 3/2023

Advagen Pharma Limited