KLOR-CON- potassium chloride powder, for solution
Upsher-Smith Laboratories, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use KLOR-CON® safely and effectively. See full prescribing information for KLOR-CON®.

KLOR-CON® Powder (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 to 100 mEq/day in 2 to 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 to 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 packet 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 Upsher-Smith Laboratories, LLC at 1-855-899-9180 or FDA at 1-800-FDA-1088 or 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: 3/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Klor-Con® powder (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

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

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 packet of potassium chloride for oral solution with 4 ounces of cold water or other beverage *[see Warnings and Precautions (5.1)]*.

Take with meals or immediately after eating.

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 packet contains 1.5 g of potassium chloride supplying 20 mEq of potassium and 20 mEq of chloride.

4 CONTRAINDICATIONS

Klor-Con powder 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 to 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 to 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 KCl with a molecular mass of 74.55.

Each packet of light orange powder contains 1.5 g of potassium chloride, USP, which is equivalent to potassium 20 mEq and chloride 20 mEq. Each packet of Klor-Con powder contains the following inactive ingredients: FD&C Yellow No. 6, malic acid, neotame, and natural orange flavor (Modified food starch (with added corn syrup), maltodextrin, citric acid, silicon dioxide and natural tocopherols).

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

Klor-Con® powder (potassium chloride for oral solution, USP) is a light orange powder available in one strength as follows:

20 mEq

Each packet contains 1.5 g of potassium chloride providing potassium 20 mEq and chloride 20 mEq supplied in:

Cartons of 30 packets	NDC 0245-0360-30
Cartons of 100 packets	NDC 0245-0360-01

Storage

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Dispense in tight, light-resistant container as defined in the USP.

PROTECT from LIGHT.

Manufactured by
UPSHER-SMITH LABORATORIES, LLC
Maple Grove, MN 55369

Klor-Con is a registered trademark of Upsher-Smith Laboratories, LLC.

Revised 0320

PRINCIPAL DISPLAY PANEL - 1.5 g Packet Carton

NDC 0245-0360-30
Klor-Con®
Powder
(Potassium Chloride
for Oral Solution, USP)

20 mEq

Orange Flavored

Each packet contains: Potassium Chloride 1.5 g

30 Single-Dose Packets
Rx only

UPSHER-SMITH

NDC 0245-0360-30

Klor-Con®
Powder
(Potassium Chloride for Oral Solution, USP)

20 mEq

Orange Flavored

Each packet contains: Potassium Chloride 1.5 g

30 Single-Dose Packets Rx only

UPSHER-SMITH

PLACE PHARMACY LABEL HERE

Usual Dose: See accompanying package insert for full prescribing information. Dosage must be adjusted to the individual needs of each patient.

Directions: Dissolve the contents of 1 packet in 4 ounces of water or other beverage.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Dispense in tight, light-resistant container as defined in the USP. PROTECT from LIGHT.

Keep out of reach of children.

NDC 0245-0360-30

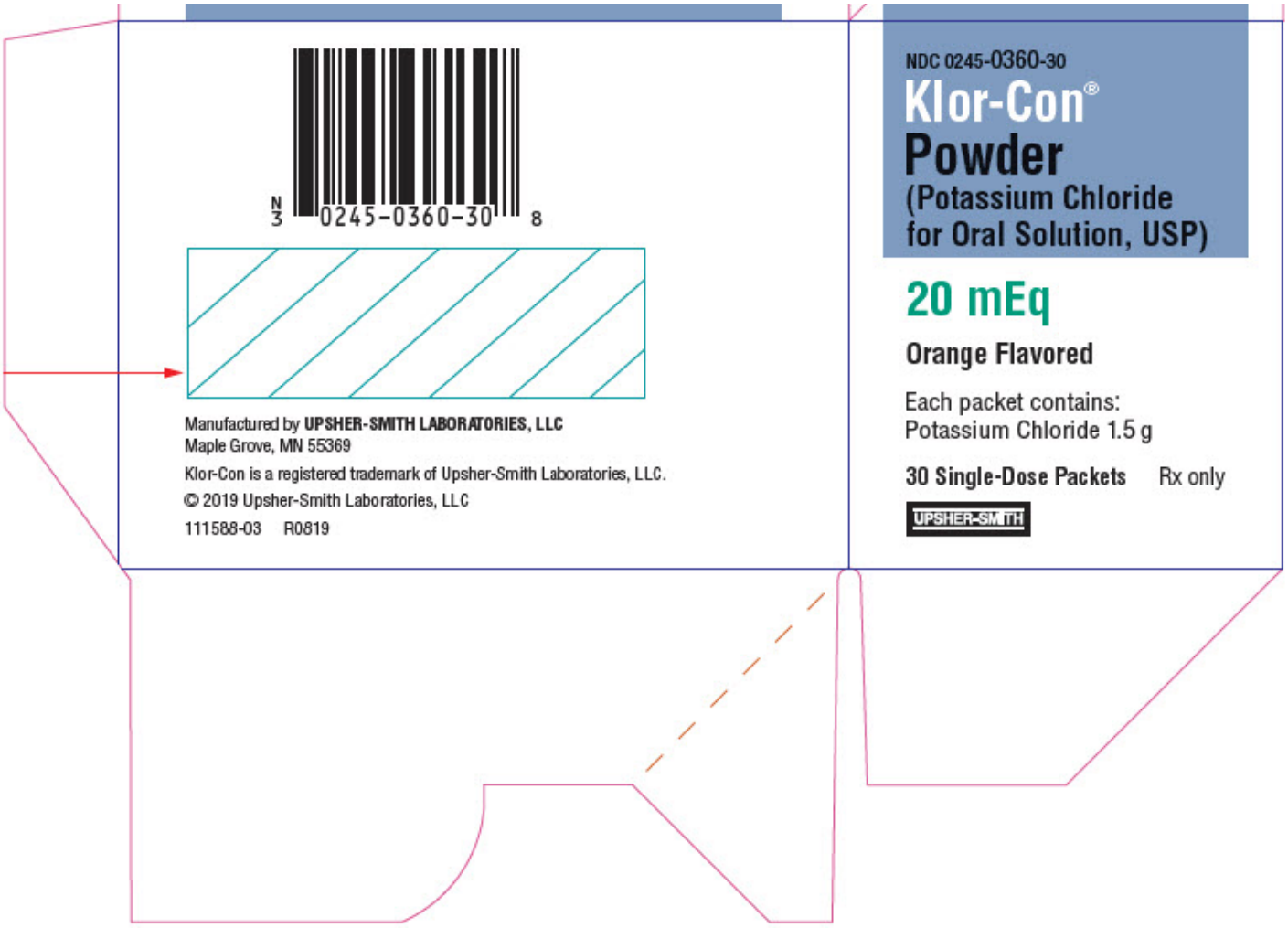
Klor-Con®
Powder
(Potassium Chloride for Oral Solution, USP)

20 mEq

Orange Flavored

30 Single-Dose Packets

UPSHER-SMITH



KLOR-CON

potassium chloride powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0245-0360
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
potassium chloride (UNII: 660YQ98I10) (potassium cation - UNII:295O53K152)	potassium chloride	1.5 g

Inactive Ingredients	
Ingredient Name	**Strength**
malic acid (UNII: 817L1N4CKP)	
neotame (UNII: VJ597D52EX)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
modified corn starch (1-octenyl succinic anhydride) (UNII: 461P5CJN6T)	

maltodextrin (UNII: 7CVR7L4A2D)	
citric acid monohydrate (UNII: 2968PHW8QP)	
tocopherol (UNII: R0ZB2556P8)	

Product Characteristics			
Color	ORANGE (light)	**Score**	
Shape		**Size**	
Flavor	ORANGE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0245-0360-30	30 in 1 CARTON	10/23/2017	
1	NDC:0245-0360-89	1 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0245-0360-01	100 in 1 CARTON	10/23/2017	
2	NDC:0245-0360-89	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209662	10/23/2017	

Labeler - Upsher-Smith Laboratories, LLC (079111820)

Establishment

Name	Address	ID/FEI	Business Operations
Upsher-Smith Laboratories, LLC		079111820	MANUFACTURE(0245-0360) , LABEL(0245-0360) , PACK(0245-0360)

Establishment

Name	Address	ID/FEI	Business Operations
Upsher-Smith Laboratories, LLC		047251004	ANALYSIS(0245-0360)

Revised: 9/2020 Upsher-Smith Laboratories, LLC