KLOR-CON/EF- potassium bicarbonate tablet, effervescent
Upsher-Smith Laboratories, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

KLOR-CON ®/EF
Potassium Bicarbonate Effervescent Tablets for Oral Solution, USP

Rx only

DESCRIPTION

Orange-flavored KLOR-CON ®/EF (potassium bicarbonate effervescent tablets for oral solution, USP) are an oral potassium supplement offered as effervescent tablets in individual packets for dissolution in water. Each tablet contains potassium bicarbonate 2.5 g and citric acid 2.1 g which in solution provides 25 mEq (978 mg) potassium as bicarbonate and citrate. Also contains: FD&C Yellow No. 6, FD&C Yellow No. 6 Lake, microcrystalline cellulose, mineral oil, orange flavor, saccharin and talc. KLOR-CON ®/EF tablets are sugar-free.

CLINICAL PHARMACOLOGY

The potassium ion 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.

Potassium depletion will occur whenever the rate of potassium loss through renal excretion and/or loss from the gastrointestinal tract exceeds the rate of potassium intake. Such depletion usually develops as a consequence of therapy with diuretics, primary or secondary hyperaldosteronism, diabetic ketoacidosis or inadequate replacement of potassium in patients on prolonged parenteral nutrition. Depletion can develop rapidly with severe diarrhea, especially if associated with vomiting. Potassium depletion due to these causes is usually accompanied by a concomitant loss of chloride and is manifested by hypokalemia and metabolic alkalosis. Potassium depletion may produce weakness, fatigue, disturbances of cardiac rhythm (primarily ectopic beats), prominent U-waves in the electrocardiogram and, in advanced cases, flaccid paralysis and/or impaired ability to concentrate urine.

If potassium depletion associated with metabolic alkalosis cannot be managed by correcting the fundamental cause of the deficiency (e.g., patients require long-term

diuretic therapy), supplemental potassium in the form of high potassium food or potassium salts may be able to restore normal potassium levels.

In rare circumstances (e.g., patients with renal tubular acidosis), potassium depletion may be associated with metabolic acidosis and hyperchloremia. In such patients, potassium replacement should be accomplished with potassium salts such as potassium bicarbonate, potassium citrate, potassium acetate or potassium gluconate.

INDICATIONS AND USAGE

1. For the treatment of patients with hypokalemia, with or without metabolic alkalosis; in digitalis intoxication; and in patients with hypokalemic familial periodic paralysis. If hypokalemia is the result of diuretic therapy, consideration should be given to the use of a lower dose of diuretic, which may be sufficient without leading to hypokalemia.
2. For the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop (e.g., digitalized patients or patients with significant cardiac arrhythmias).

The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern and when low doses of the diuretic are used. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases, and if dose adjustment of the diuretic is ineffective or unwarranted, supplementation with potassium salts may be indicated.

CONTRAINDICATIONS

Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene or amiloride) *[see **OVERDOSAGE**]* .

WARNINGS

Hyperkalemia

*[see **OVERDOSAGE**]*

In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction with Potassium-Sparing Diuretics

Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone, triamterene or amiloride), since the simultaneous administration of these agents can produce severe hyperkalemia.

Interaction with Angiotensin Converting Enzyme Inhibitors

Angiotensin converting enzyme (ACE) inhibitors (e.g., captopril, enalapril) will produce some potassium retention by inhibiting aldosterone production. Potassium supplements should be given to patients receiving ACE inhibitors only with close monitoring.

Metabolic Acidosis

Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate or potassium gluconate.

PRECAUTIONS

General

The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should be aware that acute alkalosis *per se* can produce hypokalemia in the absence of a deficit in total body potassium while acute acidosis *per se* can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease or acidosis, requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram and the clinical status of the patient.

Information for Patients

Remind the patient to take this medicine following the frequency and amount prescribed. This is especially important if the patient is also taking diuretics and/or digitalis preparations.

Laboratory Tests

When blood is drawn for analysis of plasma potassium, artifactual elevations can occur after improper venipuncture technique or as a result of *in vitro* hemolysis of the sample.

Drug Interactions

Potassium-sparing diuretics, angiotensin converting enzyme inhibitors *[see **WARNINGS**]* .

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity and fertility studies in animals have not been performed. Potassium is a normal dietary constituent.

Pregnancy

Animal reproduction studies have not been conducted with potassium salts. It is not known if potassium salts cause fetal harm when administered to a pregnant woman or affect reproductive capacity. Potassium supplements should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from oral potassium supplements, a decision should be made whether to discontinue nursing or discontinue the drug, considering the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

One of the most severe adverse effects is hyperkalemia *[see **CONTRAINDICATIONS, WARNINGS** and **OVERDOSAGE**]* .

The most common adverse reactions to oral potassium salts are nausea, vomiting, flatulence, abdominal pain/discomfort and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by diluting the preparation further, taking the dose with meals or reducing the dose.

OVERDOSAGE

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 intravenously, potentially fatal hyperkalemia can result *[see **CONTRAINDICATIONS** and **WARNINGS**]* . It is important to recognize that 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-wave, 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).

Treatment measures for hyperkalemia include the following: 1) elimination of foods and medications containing potassium and elimination of potassium-sparing diuretics; 2) intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1,000 mL; 3) correction of acidosis, if present, with intravenous sodium bicarbonate; 4) use of exchange resins, hemodialysis or peritoneal dialysis.

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

DOSAGE AND ADMINISTRATION

The usual dietary potassium intake by the average adult is 50 to 100 mEq per day. Potassium depletion sufficient to cause hypokalemia usually requires the loss of 200 mEq or more of potassium from the total body store.

Dosage must be adjusted to the individual needs of each patient. The dose for the prevention of hypokalemia is typically 25 mEq per day. Doses of 50 to 100 mEq per day or more are used for the treatment of potassium depletion. Dosage should be divided if more than 25 mEq per day is given such that no more than 25 mEq is given in a single dose.

The usual adult dose is 25 to 100 mEq of potassium per day (one KLOR-CON ®/EF tablet 1 to 4 times daily after meals).

Each KLOR-CON ®/EF tablet should be dissolved in at least 4 ounces of cold or ice water. These preparations, like other potassium supplements, must be properly diluted to avoid the possibility of gastrointestinal irritation.

HOW SUPPLIED

KLOR-CON ®/EF Potassium Bicarbonate Effervescent Tablets for Oral Solution, USP are supplied as follows:

- Cartons of 30 individually wrapped tablets NDC 0245-5326-30
- Cartons of 100 individually wrapped tablets NDC 0245-5326-01

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Manufactured for
UPSHER-SMITH LABORATORIES, LLC
Maple Grove, MN 55369
by Nomax, Inc.
St. Louis, MO 63123

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

Revised: 6/2020

PRINCIPAL DISPLAY PANEL - 978 mg Tablet Pouch Carton

NDC 0245-5326-30

KLOR-CON ®/EF

Potassium Bicarbonate
Effervescent Tablets
for Oral Solution, USP

Orange-Flavored

25 mEq (978 mg)
Potassium per Tablet

30 Tablets

Rx only

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NDC 0245-5326-30

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Potassium Bicarbonate Effervescent Tablets for Oral Solution, USP

Orange-Flavored

25 mEq (978 mg)

Potassium per Tablet

30 Tablets

Rx only

UPSHER-SMITH

PLACE PHARMACY LABEL HERE

Each tablet in solution provides: 25 mEq (978 mg) potassium (supplied by 2.5 g potassium bicarbonate) and 2.1 g citric acid.

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

Directions: Allow tablet to dissolve completely in 4 ounces of cold water before drinking.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

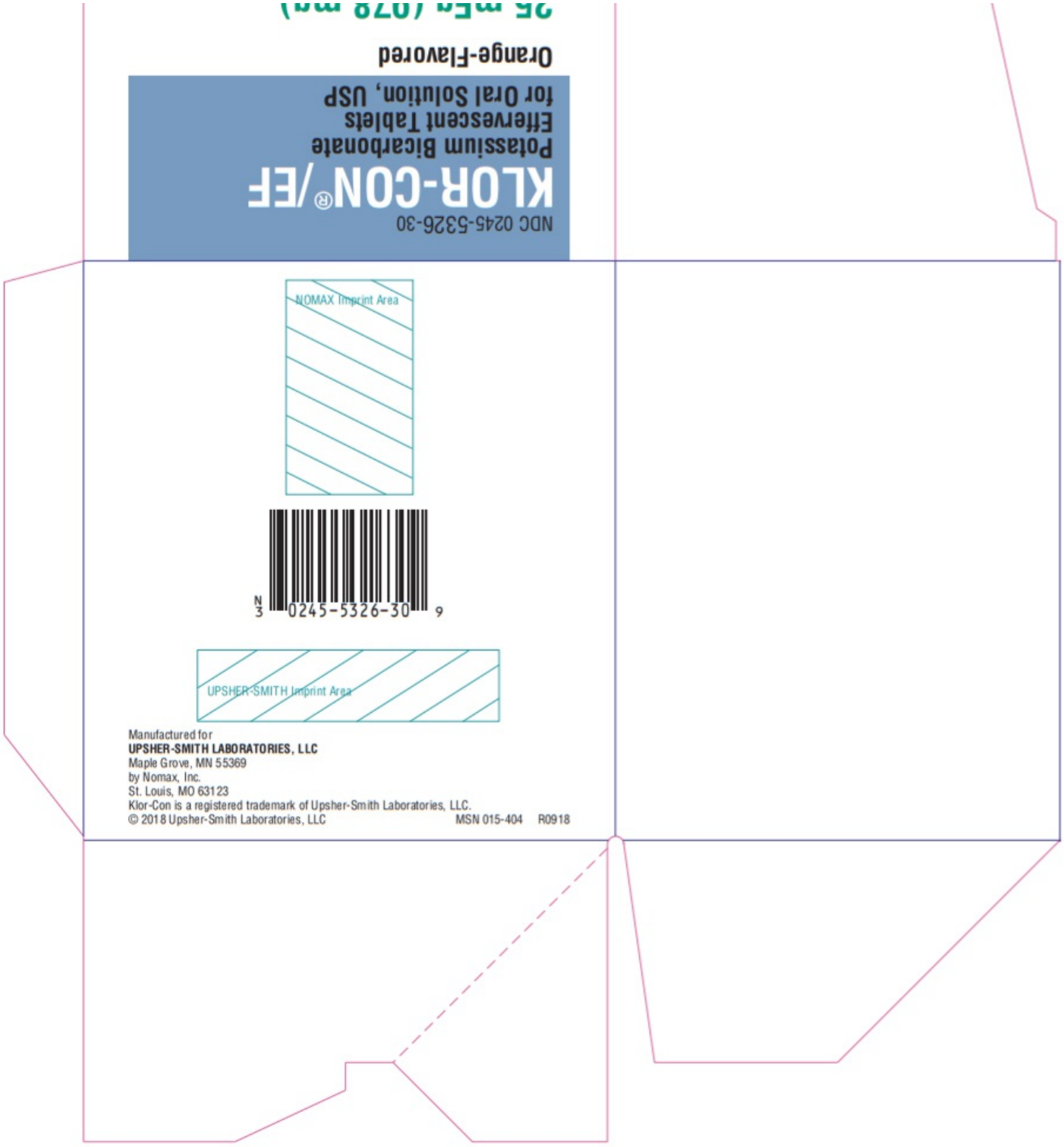
Keep out of reach of children.

UPSHER-SMITH

30 Tablets

Potassium per Tablet

25 mEq (978 mg)



KLOR-CON/EF

potassium bicarbonate tablet, effervescent

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0245-5326
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	978 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
SACCHARIN (UNII: FST467XS7D)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	25mm
Flavor	ORANGE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0245-5326-30	30 in 1 CARTON	06/21/2019	
1	NDC:0245-5326-89	1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0245-5326-01	100 in 1 CARTON	06/21/2019	
2	NDC:0245-5326-89	1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/01/2014	

Labeler - Upsher-Smith Laboratories, Inc. (047251004)

Establishment

Name	Address	ID/FEI	Business Operations
Nomax Inc.		103220273	manufacture(0245-5326)