EFFER-K UNFLAVORED- potassium bicarbonate tablet, effervescent
EFFER-K ORANGE- potassium bicarbonate tablet, effervescent
EFFER-K LEMON CITRUS- potassium bicarbonate tablet, effervescent
EFFER-K CHERRY BERRY- potassium bicarbonate tablet, effervescent
Nomax 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.

Effer-K®
25 mEq

Description

Description: Effer-K® 25 mEq TABLETS (Potassium Bicarbonate Effervescent Tablets for Oral Solution, USP) are intended for the preparation of an oral solution of potassium. Each tablet contains 2.5 g. potassium bicarbonate and 2.1 g. citric acid which in solution provides 25 mEq (978 mg) of elemental potassium as potassium citrate. Tablets also contain: SD flavors, microcrystalline cellulose, mineral oil, saccharine and talc. The orange tablets contain FD&C yellow No. 6 and FD&C yellow No, 6 lake. The lemon citrus tablets contain D&C yellow No. 10 and yellow No. 10 lake. The cherry berry tablets contain FD&C red No. 40 and FD&C red No. 40 lake. The unflavored tablets do not contain any natural or synthetic dyes, flavors or sweeteners.

Tablets are one inch in diameter round, flat face on both sides with large bevels. "EK-25" is imprinted on one side of the tablets. Each tablet is foil-pouched with the product description on one side of the pouch and the lot number, expiration and barcode on the other.

Clinical Pharmacology

Potassium ion is the principal intracellular cation of most body tissues, whereas sodium ion is relatively low in concentration. In extracellular fluid the opposite exists, sodium ion being principal and potassium ion being low. The situation is maintained by an active membrane-bound enzyme (Na^+K^+ATPase). This potassium ion concentration gradient is essential to conduct nerve impulses in such specialized tissues as the brain, heart, and skeletal muscle; and in addition, to maintain normal renal function, acid-base balance, and various cellular metabolic functions. Elimination values are 90% renal and 10% fecal.

Potassium depletion may occur if the rate of potassium ion loss by renal excretion and/or loss from the gastrointestinal tract exceeds the rate of potassium ion intake. Such depletion usually develops slowly as a consequence of prolonged therapy with oral diuretics, primary or secondary hyperaldosteronism, diabetic ketoacidosis, severe diarrhea, or inadequate replacement of potassium in patients on prolonged parenteral nutrition. Potassium depletion due to these causes is usually accompanied by a concomitant deficiency of chloride and is manifested by hypokalemia and metabolic alkalosis. Potassium depletion may produce weakness, fatigue, mood or mental changes, nausea, vomiting, 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.

Indications and Usage

1. For therapeutic use in patients with hypokalemia with or without metabolic alkalosis; in chronic digitalis intoxication; and in patients with hypokalemic familial periodic paralysis.
2. For prevention of potassium depletion when the dietary intake of potassium ion is inadequate in the following conditions; patients receiving digitalis and diuretics for congestive heart failure; hepatic cirrhosis with ascites; states of aldosterone excess with normal renal function; potassiumlosing

nephropathy, and certain diarrheal states; long-term corticosteroid therapy.

3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension or receiving certain antibiotics is often unnecessary when such patients have a normal dietary pattern. 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 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. Conditions predisposing to hyperkalemia include: chronic renal failure, acute metabolic acidosis, uncontrolled diabetes mellitus, esophageal compression or delayed gastric emptying or intestinal obstruction/stricture or peptic ulcer. Potassium supplements should be used with caution and only where medically indicated in patients with familial periodic paralysis, myotonia congenita or severe/complete heart block. IMPORTANT: Potassium supplements are contraindicated in patients receiving potassium-sparing diuretics (e.g. spironolactone, triamterene) since such use may produce severe hyperkalemia.

Warnings

In patients with hyperkalemia and 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.

Note: There is no conclusive evidence that potassium supplements lower blood pressure in hypertensive patients.

Precautions

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 bear in mind 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

To minimize the possibility of gastrointestinal irritation associated with the oral ingestion of concentrated potassium salt preparations, patients should be directed to dissolve each dose completely in the stated amount of water.

Each dose should be taken immediately after a meal or with food. Patients should avoid low-salt foods and salt substitutes, unless approved by physician. The patient should be cautioned to comply strictly with the regimen, particularly when taking diuretics or digitalis, to visit the physician regularly and to report at once any unusual symptoms (e.g. blackish stools, a sign of gastrointestinal bleeding). As with any other medicine, the patient should be counseled on this background information and advised to report to the physician any changes in routine (e.g. starting a fitness program). Proper storage and

handling of the product is important. Tablets should not be removed from foil pouch until shortly before use.

Laboratory tests

Frequent clinical evaluation of the patient should include an ECG and a serum potassium level; also, as appropriate, renal function, serum magnesium and serum pH.

Drug Interactions

The simultaneous administration of potassium supplements and a potassium-sparing diuretic can produce severe hyperkalemia (see Contraindications). Potassium supplements should be used cautiously in patients who are using salt substitutes, because most of the latter contain substantial amounts of potassium. Such concomitant use could result in hyperkalemia.

Moreover, the following drugs may produce unfavorable interactions when used concomitantly with potassium supplements: angiotension-converting enzyme (ACE) inhibitors, nonsteroid anti-inflammatory drugs (NSAIDs), beta-adrenergic blocking drugs, heparin, low-salt foods, other potassium containing medications, digitalis glycosides and others.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Potassium is an essential constituent of the human diet. There are no data available on long-term potential for carcinogenicity, mutagenicity, or impairment of fertility in animals or in human beings.

Usage in Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with ***Effer-K***® 25mEq TABLETS (Potassium Bicarbonate Effervescent Tablets for Oral Solution, USP). It is also not known whether these products can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ***Effer-K***® 25mEq TABLETS (Potassium Bicarbonate Effervescent Tablets for Oral Solution, USP) should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Information unknown.

Nursing Mothers

Although no studies have been done, it is presumed that potassium is excreted in human milk. Caution should be exercised when ***Effer-K***® 25mEq TABLETS (Potassium Bicarbonate Effervescent Tablets for Oral Solution, USP) are administered to a nursing woman.

Usage in Children

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, abdominal 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. Skin rash has been reported rarely.

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 initally hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration 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.

Treatment measures for hyperkalemia include the elimination of foods and medications containing potassium and potassium-sparing diuretics, as well as ACE inhibitors, beta blocking agents, NSAIDs, heparin, and cyclosporine. In cases of life-threatening hyperkalemia, treatment measures may include: (1) intravenous administration of 300 to 500 ml/hr of 10% dextrose solution containing 10-20 units of insulin per 1,000 ml; (2) correction of acidosis, if present, with intravenous sodium bicarbonate; (3) use of exchange resins, hemodialysis, or peritoneal dialysis; (4) administration of a calcium salt to antagonize the cardiotoxic effects in patients whose electrocardiograms show appropriate characteristics, and who are not receiving digitalis glycosides; and (5) maintenance of a high urine output in suitable patients.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, rapid lowering of serum potassium can produce digitalis toxicity.

Dosage and administration

Dosage and Administration: Adults- One ***Effer-K***® flavored tablet, (Orange, Lemon Citrus or Cherry Berry) each containing 25 mEq (978 mg) of potassium, completely dissolved in 4 ounces of cold or ice water, 1 to 4 times daily, depending on the requirement of the patient. For ***Effer-K***® unflavored tablets (each containing 25 mEq (978 mg) of potassium) we recommend completely dissolving one tablet in 12 to 16 ounces of cold juice of the patient's choice.

NOTE: It is suggested that any effervescent potassium tablets be taken with meals and sipped slowly over a 5 to 10 minute period.

How Supplied

Effer-K® 25 mEq TABLETS (Potassium Bicarbonate Effervescent Tablets for Oral Solution, USP). Each tablet in solution provides 25 mEq of elemental potassium as potassium citrate. Store below 40˚C (104˚F) preferably between 15˚ and 30˚C (59˚ and 86˚F), in original hermetic packaging.

Tablets are one inch diameter round, flat face on both sides with large bevels. "EK 25" is imprinted one side of the tablets. Each tablet is pouched with the product description on one side of the pouch and the lot number, expiration date, and barcode on the other.

NDC 51801-001-30 Orange-flavored, package of 30 tablets.

NDC 51801-001-40 Orange-flavored, package of 100 tablets.

NDC 51801-005-30 Lemon Citrus-flavored, package of 30 tablets.

NDC 51801-006-30 Cherry Berry-flavored, package of 30 tablets.

NDC 51801-007-30 Unflavored, package of 30 tablets.

Nomax, Inc. St. Louis, MO 63123 - Made in USA
MSN 015-031

Rev. 08/10

PRINCIPAL DISPLAY PANEL - 30 Tablet Pouch Carton - Unflavored

NDC 51801-007-30
30 Tablets

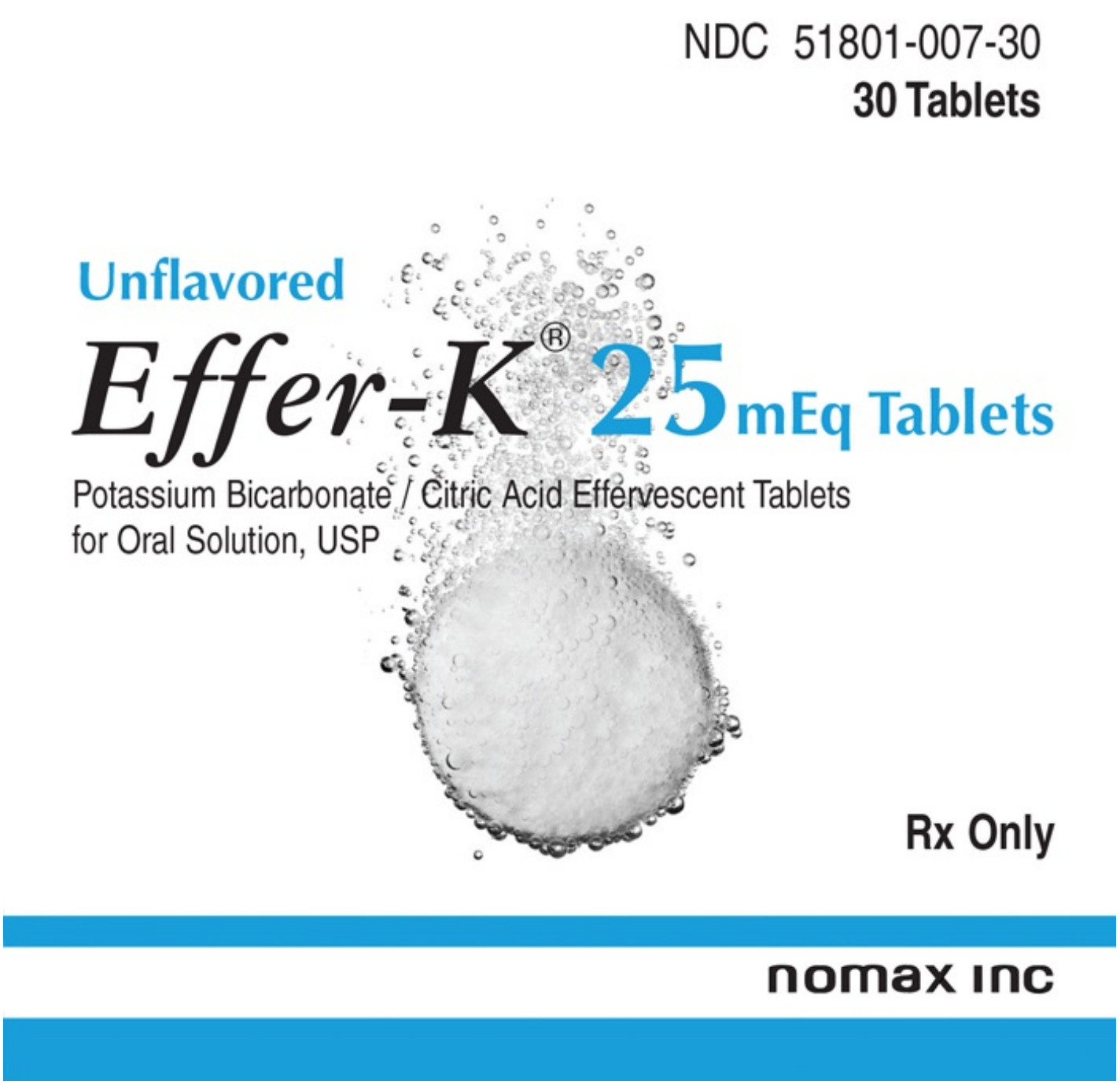
Effer-K® 25 mEq Tablets

POTASSIUM BICARBONATE EFFERVESCENT TABLETS FOR ORAL SOLUTION, USP

Each Tablet contains 25mEq (978 mg) of Potassium

Unflavored (Dissolve in 12-16 ounces of juice)
Rx Only

nomax inc



PRINCIPAL DISPLAY PANEL - 30 Tablet Pouch Carton - Orange

NDC 51801-001-30
30 Tablets

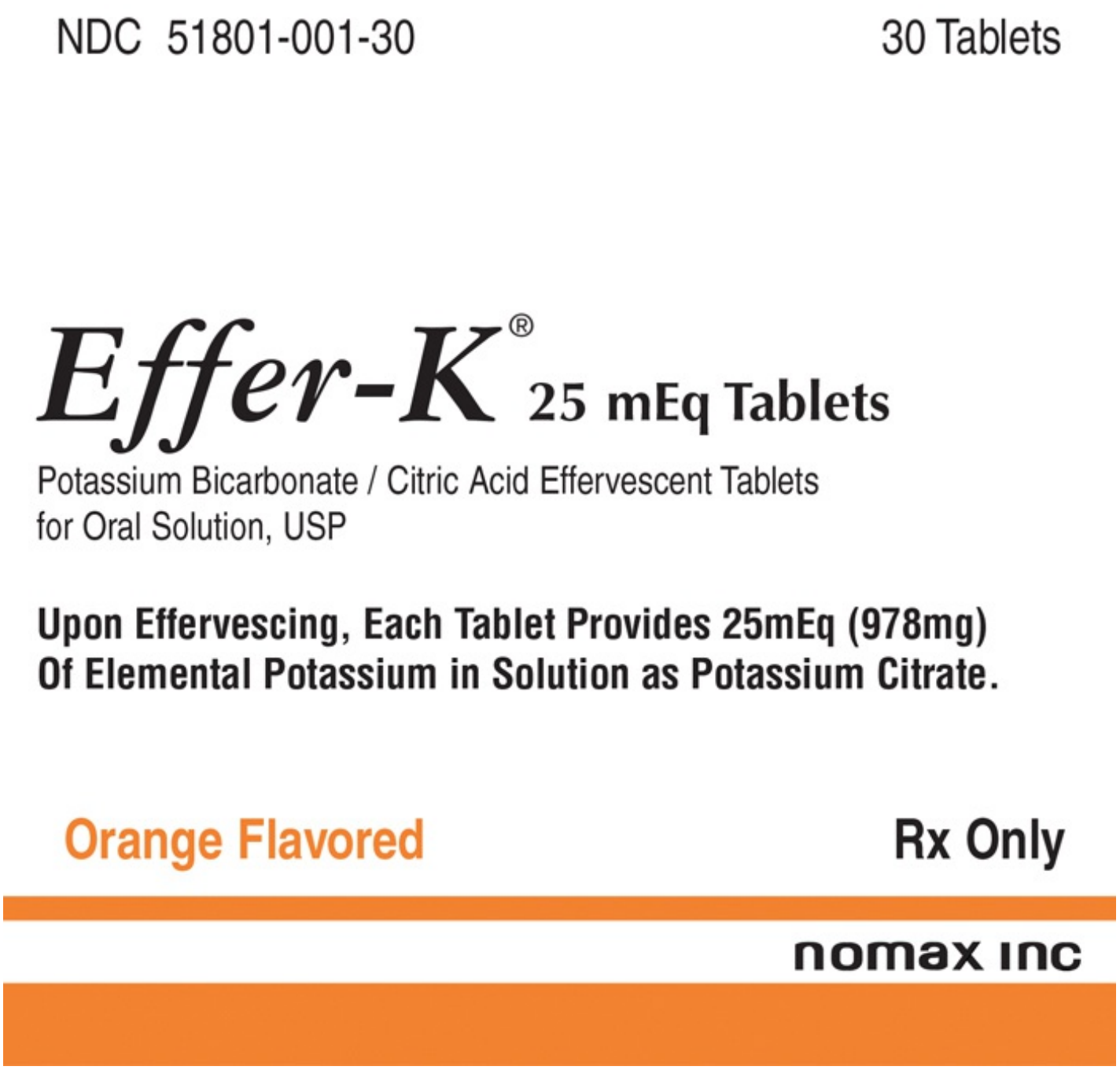
Effer-K® 25 mEq Tablets

POTASSIUM BICARBONATE EFFERVESCENT TABLETS FOR ORAL SOLUTION, USP

Each Tablet contains 25mEq (978 mg) of Potassium

Orange Flavored
Rx Only

nomax inc



PRINCIPAL DISPLAY PANEL - 30 Tablet Pouch Carton - Lemon

NDC 51801-005-30
30 Tablets

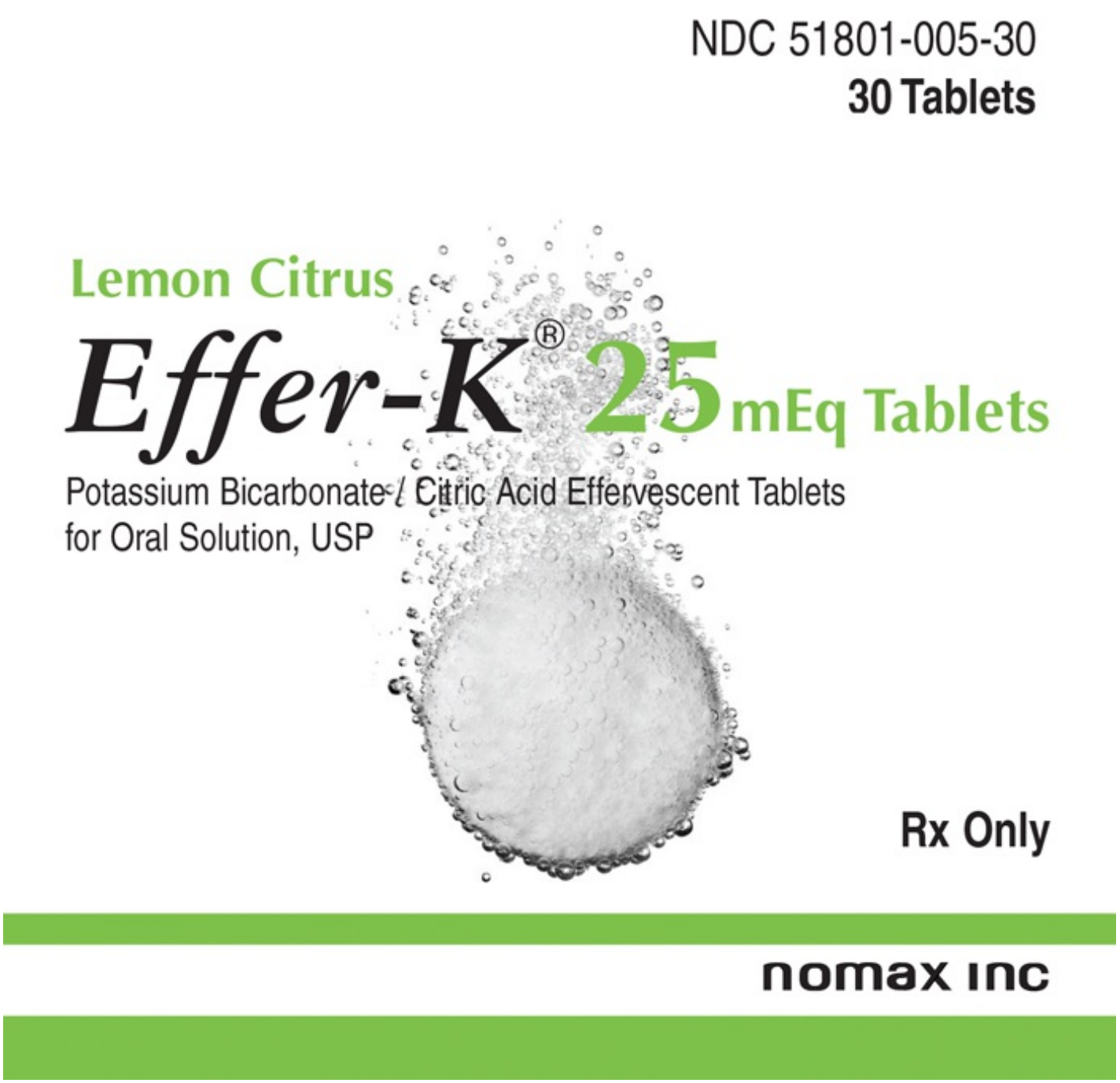
Effer-K® 25 mEq Tablets

POTASSIUM BICARBONATE EFFERVESCENT TABLETS FOR ORAL SOLUTION, USP

Each Tablet contains 25mEq (978 mg) of Potassium

Lemon Citrus Flavored
Rx Only

nomax inc



PRINCIPAL DISPLAY PANEL - 30 Tablet Pouch Carton - Cherry

NDC 51801-006-30
30 Tablets

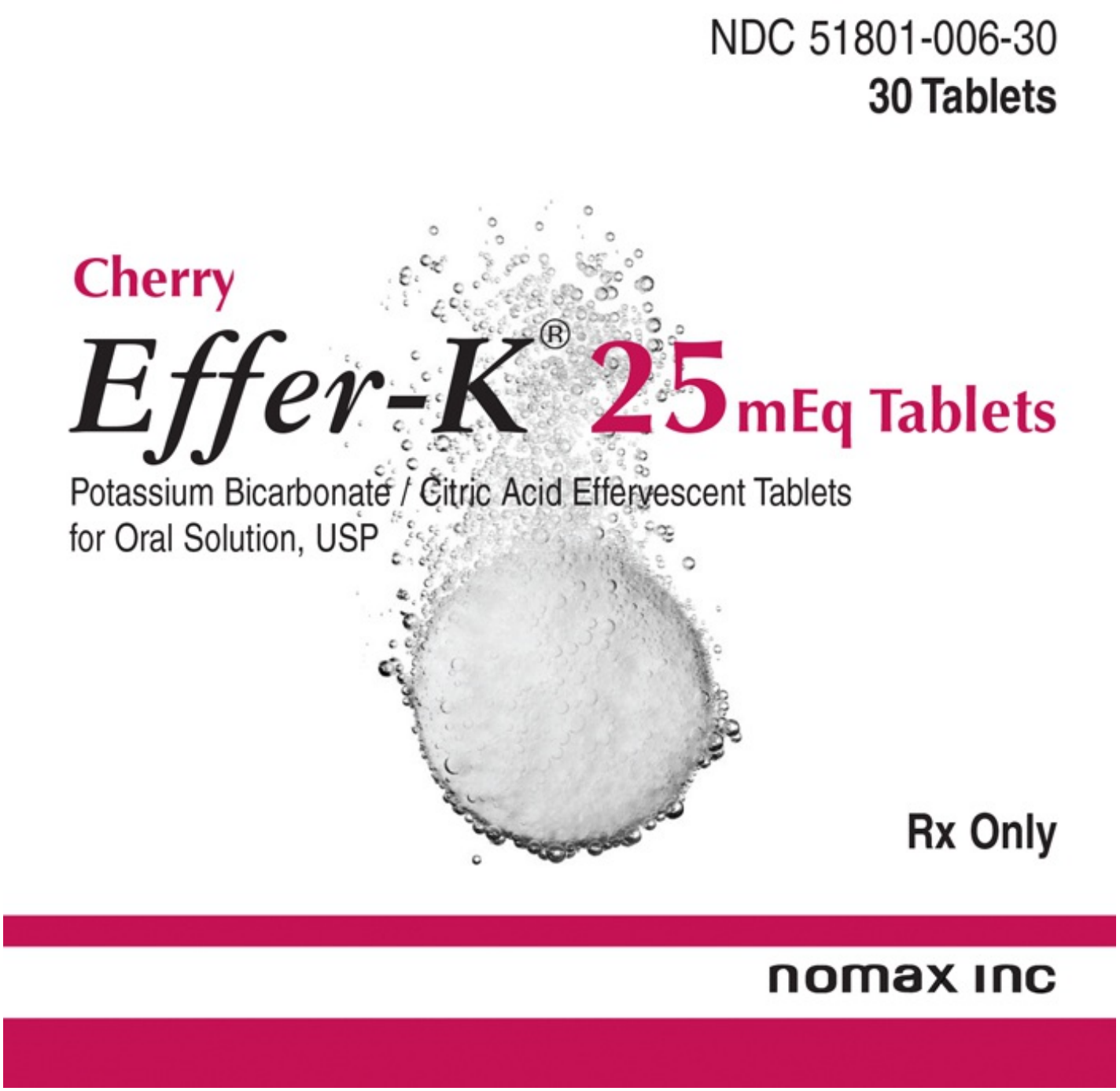
Effer-K® 25 mEq Tablets

POTASSIUM BICARBONATE EFFERVESCENT TABLETS FOR ORAL SOLUTION, USP

Each Tablet contains 25mEq (978 mg) of Potassium

Cherry Berry Flavored
Rx Only

nomax inc



EFFER-K UNFLAVORED

potassium bicarbonate tablet, effervescent

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51801-007
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (BICARBONATE ION - UNII:HN1ZRA3Q20)	POTASSIUM BICARBONATE	977.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	2100 mg
MINERAL OIL (UNII: T5L8T28FGP)	34 mg
TALC (UNII: 7SEV7J4R1U)	20 mg
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	100 mg

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	25mm
Flavor		**Imprint Code**	EK;25
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51801-007-30	30 in 1 CARTON	01/30/2013	
1		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		01/30/2013	

EFFER-K ORANGE

potassium bicarbonate tablet, effervescent

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51801-001

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (BICARBONATE ION - UNII:HN1ZRA3Q20)	POTASSIUM BICARBONATE	977.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	2100 mg
MINERAL OIL (UNII: T5L8T28FGP)	34 mg
TALC (UNII: 7SEV7J4R1U)	20 mg
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	100 mg

Product Characteristics			
Color	ORANGE	**Score**	2 pieces
Shape	ROUND	**Size**	25mm
Flavor	ORANGE	**Imprint Code**	EK;25
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51801-001-30	30 in 1 CARTON	01/30/2013	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:51801-001-40	100 in 1 CARTON	01/30/2013	
2		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		01/30/2013	

EFFER-K LEMON CITRUS

potassium bicarbonate tablet, effervescent

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51801-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (BICARBONATE ION - UNII:HN1ZRA3Q20)	POTASSIUM BICARBONATE	977.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	2100 mg
MINERAL OIL (UNII: T5L8T28FGP)	34 mg
TALC (UNII: 7SEV7J4R1U)	20 mg
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	100 mg

Product Characteristics			
Color	YELLOW	**Score**	2 pieces
Shape	ROUND	**Size**	25mm
Flavor	LEMON (Lemon Citrus)	**Imprint Code**	EK;25
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51801-005-30	30 in 1 CARTON	01/30/2013	
1		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		01/30/2013	

EFFER-K CHERRY BERRY

potassium bicarbonate tablet, effervescent

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51801-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (BICARBONATE ION - UNII:HN1ZRA3Q20)	POTASSIUM BICARBONATE	977.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	2100 mg

MINERAL OIL (UNII: T5L8T28FGP)	34 mg
TALC (UNII: 7SEV7J4R1U)	20 mg
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	100 mg

Product Characteristics			
Color	PINK	**Score**	2 pieces
Shape	ROUND	**Size**	25mm
Flavor	CHERRY (Cherry Berry)	**Imprint Code**	EK;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51801-006-30	30 in 1 CARTON	01/30/2013	
1		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		01/30/2013	

Labeler - Nomax Inc. (103220273)

Establishment

Name	Address	ID/FEI	Business Operations
Nomax Inc.		103220273	MANUFACTURE(51801-007, 51801-001, 51801-005, 51801-006)

Revised: 12/2019 Nomax Inc.