EFFER-K 10 MEQ UNFLAVORED- potassium bicarbonate tablet, effervescent
EFFER-K 10 MEQ CHERRY VANILLA- potassium bicarbonate tablet, effervescent
EFFER-K 20 MEQ UNFLAVORED- potassium bicarbonate tablet, effervescent
EFFER-K 20 MEQ ORANGE CREAM- 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

Description

Effer-K® 10mEq and 20 mEq Tablets (Effervescent Potassium Bicarbonate/ Citric Acid Tablets for Oral Solution, USP) are intended for the preparation of an oral solution of potassium.

Each 10 mEq tablet contains 1.0g potassium bicarbonate and 0.84g citric acid which, after effervescing, provides a solution containing 10 mEq (391 mg) of elemental potassium as potassium citrate.

Each 20 mEq tablet contains 2.0g potassium bicarbonate and 1.68g citric acid which, after effervescing, provides a solution containing 20 mEq (782 mg) of elemental potassium as potassium citrate.

Tablets also contain maltodextrin, anhydrous dextrose and l-leucine. In addition, the flavored tablets contain SD flavors, and sucralose.

The 10 mEq Cherry Vanilla tablets contain FD&C Red #40 and the 20 mEq Orange Cream tablets contain FD&C Yellow #6 and FD&C Red #40. The Unflavored 10 and 20 mEq tablets do not contain any natural or synthetic dyes, flavors or sweeteners.

The 10 mEq tablets are 11/16 inch diameter round, flat face on both sides with large bevels. EK 10 is imprinted on one side. The 20 mEq tablets are 7/8 inch diameter round, flat face on both sides with large bevels. EK 20 is imprinted on one side. Each tablet is pouched with the product description on one side of the pouch and the lot number, expiration date and bar code 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; potassium-losing 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***® 10mEq or 20 mEq Tablets (Effervescent Potassium Bicarbonate/ Citric Acid Tablets for Oral Solution, USP). It is also not known whether these products can cause fetal harm when administered to pregnant women or can affect reproduction capacity. ***Effer-K***®10mEq or 20mEq Tablets (Effervescent Potassium Bicarbonate/ Citric Acid 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***® 10mEq or 20mEq Tablets (Effervescent Potassium Bicarbonate/ Citric Acid 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

Effer-K® 10 mEq. Adults - one tablet (Cherry Vanilla or Unflavored) each containing 10 mEq. (391 mg) of elemental potassium, 1 to 4 times daily, depending on the requirement of the patient. Completely dissolve the Cherry Vanilla flavored tablet in 2 to 3 ounces (58 to 85 mL) of cold or ice water before drinking. Completely dissolve the Unflavored tablet in 2 to 3 ounces (58 to 85 mL) of cold juice of choice before drinking.

Effer-K® 20 mEq. Adults - one tablet (Orange Cream or Unflavored) each containing 20 mEq. (782 mg) of elemental potassium, 1 to 4 times daily, depending on the requirement of the patient. Completely dissolve the Orange Cream flavored tablet in 3 to 4 ounces (85 to 115 mL) of cold or ice water before drinking. Completely dissolved the Unflavored tablet in 3 to 4 ounces (85 to 115 mL) of cold juice of choice before drinking.

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

How Supplied

Each tablet of ***Effer-K***® 10 mEq Tablets (Effervescent Potassium Bicarbonate/ Citric Acid Tablets for Oral Solution, USP) in solution provides 10 mEq (391 mg) of elemental potassium as potassium citrate.

Each tablet of ***Effer-K***® 20 mEq Tablets (Effervescent Potassium Bicarbonate/ Citric Acid Tablets for Oral Solution, USP) in solution provides 20 mEq (782 mg) 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 package.

The 10 mEq tablets are 11/16 inch diameter round, flat face on both sides with large bevels. EK 10 is imprinted on one side of the tablet. 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.

The 20 mEq tablets are 7/8 inch diameter round, flat face on both sides with large bevels. EK 20 is

imprinted on one side of the tablet. 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 51801-01330 Unflavored, 10 mEq, package of 30 tablets
NDC 51801-01430 Cherry Vanilla, 10 mEq, package of 30 tablets
NDC 51801-01130 Unflavored, 20 mEq, package of 30 tablets
NDC 51801-01230 Orange Cream, 20 mEq, package of 30 tablets

Nomax, Inc. St. Louis, MO 63123 - Made in USA
MSN 015-183

Rev. 05/12

PRINCIPAL DISPLAY PANEL - 10mEq Tablet Pouch Carton - Unflavored

NDC 51801-013-30
30 Tablets

***Effer-K*® 10mEq Tablets**

POTASSIUM BICARBONATE / CITRIC ACID EFFERVESCENT TABLETS FOR ORAL SOLUTION, USP

Upon effervescing, each tablet provides 10mEq (391mg)
of potassium in solution as potassium citrate.

Unflavored
Rx Only

nomax inc

PRINCIPAL DISPLAY PANEL - 10 mEq Tablet Pouch Carton - Cherry Vanilla

NDC 51801-014-30
30 Tablets

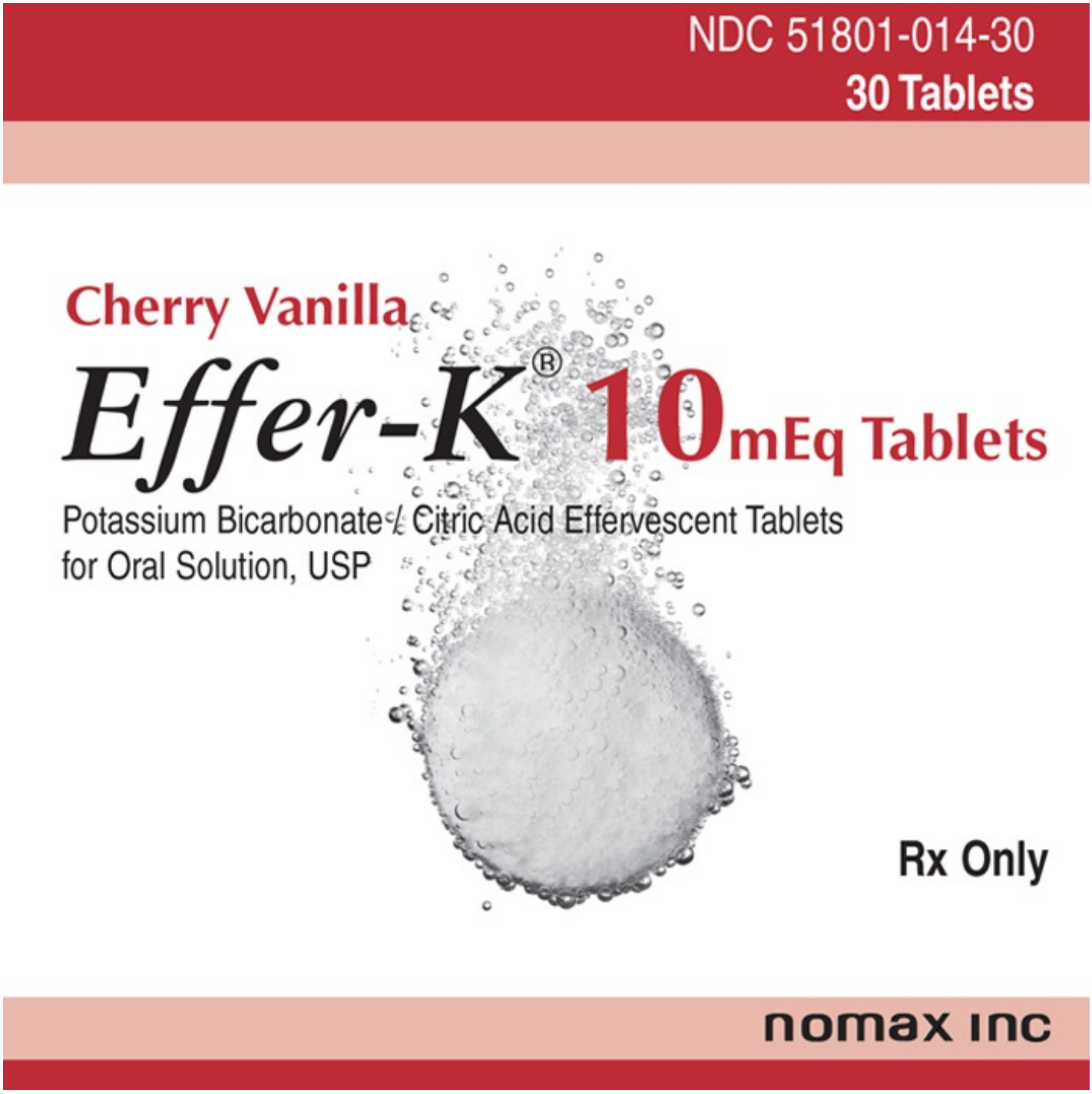
***Effer-K*® 10 mEq Tablets**

POTASSIUM BICARBONATE / CITRIC ACID EFFERVESCENT TABLETS FOR ORAL SOLUTION, USP

Upon effervescing, each tablet provides 10mEq (391mg) of potassium in solution as potassium citrate.

Cherry Vanilla
Rx Only

nomax inc



PRINCIPAL DISPLAY PANEL - 20 mEq Tablet Pouch Carton - Unflavored

NDC 51801-011-30
30 Tablets

***Effer-K*® 20 mEq Tablets**

POTASSIUM BICARBONATE / CITRIC ACID EFFERVESCENT TABLETS FOR ORAL SOLUTION, USP

Upon effervescing, each tablet provides 20mEq (782mg)
of potassium in solution as potassium citrate.

Unflavored

Rx Only

nomax inc

PRINCIPAL DISPLAY PANEL - 20mEq Tablet Pouch Carton - Orange Cream

NDC 51801-012-30
30 Tablets

***Effer-K*® 20mEq Tablets**

POTASSIUM BICARBONATE / CITRIC ACID EFFERVESCENT TABLETS FOR ORAL SOLUTION, USP

Upon effervescing, each tablet provides 20mEq (782mg)
of potassium in solution as potassium citrate.

Orange Cream
Rx Only

nomax inc

EFFER-K 10 MEQ UNFLAVORED

potassium bicarbonate tablet, effervescent

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51801-013
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	391 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	840 mg
MALTODEXTRIN (UNII: 7CVR7L4A2D)	64.5 mg
DEXTROSE (UNII: IY9XDZ35W2)	17.5 mg
LEUCINE (UNII: GMW67QNF9C)	45 mg

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	17mm
Flavor		**Imprint Code**	EK;10
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51801-013-30	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 10 MEQ CHERRY VANILLA

potassium bicarbonate tablet, effervescent

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51801-014
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	391 mg

Inactive Ingredients	
Ingredient Name	**Strength**

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	840 mg
MALTODEXTRIN (UNII: 7CVR7L4A2D)	17.5 mg
DEXTROSE (UNII: IY9XDZ35W2)	17.5 mg
LEUCINE (UNII: GMW67QNF9C)	45 mg

Product Characteristics			
Color	PINK	**Score**	2 pieces
Shape	ROUND	**Size**	17mm
Flavor	CHERRY (Cherry Vanilla)	**Imprint Code**	EK;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51801-014-30	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 20 MEQ UNFLAVORED

potassium bicarbonate tablet, effervescent

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51801-011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	782 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	1680 mg
MALTODEXTRIN (UNII: 7CVR7L4A2D)	129 mg
DEXTROSE (UNII: IY9XDZ35W2)	35 mg
LEUCINE (UNII: GMW67QNF9C)	90 mg

Product Characteristics

Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	22mm
Flavor		**Imprint Code**	EK;20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51801-011-30	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 20 MEQ ORANGE CREAM

potassium bicarbonate tablet, effervescent

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51801-012
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	782 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	1680 mg
MALTODEXTRIN (UNII: 7CVR7L4A2D)	35 mg
DEXTROSE (UNII: IY9XDZ35W2)	35 mg
LEUCINE (UNII: GMW67QNF9C)	90 mg

Product Characteristics

Color	ORANGE	**Score**	2 pieces
Shape	ROUND	**Size**	22mm
Flavor	ORANGE (Orange Cream)	**Imprint Code**	EK;20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51801-012-30	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(51801-013, 51801-014, 51801-011, 51801-012)

Revised: 12/2019 Nomax Inc.