KAOPECTATE REGULAR STRENGTH VANILLA FLAVOR ANTI DIARRHEAL - bismuth subsalicylate liquid
Physicians Total Care, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Kaopectate Vanilla Flavor Anti-Diarrheal

Active Ingredient *(per 15mL)*:

Bismuth subsalicylate 262 mg

Purpose

Anti-diarrheal

Upset stomach reliever

Uses

- relieves diarrhea
- relieves nausea and upset stomach associated with this symptom

Warnings

Reye's Syndrome:

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy Alert: Contains salicylate.

Do not take if you are

- allergic to salicylates (including aspirin)
- taking other salicylate products

Do not use if you have

- an ulcer
- a bleeding problem
- bloody or black stool

Ask a doctor before use if you have

- fever
- mucus in the stool

Ask a doctor or pharmacist before use if you are taking any drug for

- diabetes
- gout
- arthritis
- anticoagulation (thinning the blood)

When using this product

a temporary, but harmless, darkening of the stool and/or tongue may occur

Stop use and ask a doctor if

- symptoms get worse
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **shake well immediately before each use**
- adults and children 12 years of age and older: 30 mL or 2 tablespoonfuls
- for accurate dosing, use convenient pre-measured dose cup
- repeat dose every 1/2 hour to 1 hour as needed
- do not exceed 8 doses in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other Information

- **each 15 mL tablespoonful contains:** sodium 4 mg
- **each 15 mL tablespoonful contains:** total salicylates 130 mg
- **do not use if inner seal is broken or missing**
- **low sodium**

Inactive Ingredients

caramel, carboxymethylcellulose sodium, flavor, microcrystalline cellulose, sodium salicylate, sorbic acid, sucrose, water, xanthan gum (245-241)

Dist. by CHATTEM, INC.

P.O. Box 2219

Chattanooga, TN 37409 USA

Made in Canada

CHATTEM® www.chattem.com

Additional barcode labeling by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

Principal Display Panel

Kaopectate®

- **Anti-Diarrheal**
- **Upset Stomach Reliever**

Bismuth Subsalicylate

Goes to the Source to Help Relieve Diarrhea

Contains Salicylates

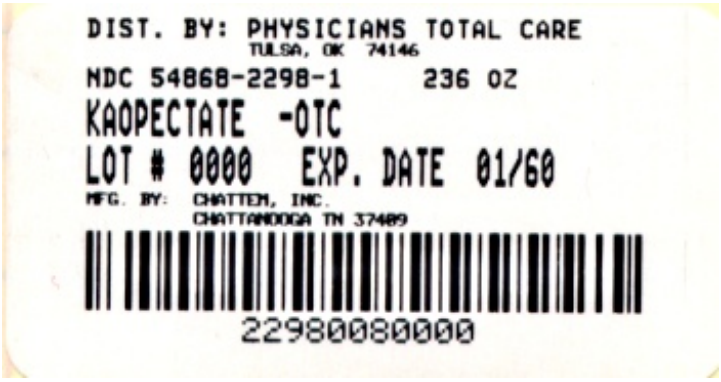
Vanilla

Regular Flavor

262 mg bismuth subsalicylate per 15 mL

8 fl oz (236 mL)

NDC 54868-2298-1



KAOPECTATE REGULAR STRENGTH VANILLA FLAVOR ANTI DIARRHEAL

bismuth subsalicylate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54868-2298(NDC:41167-4000)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH SUBSALICYLATE - UNII:62TEY51RR1)	BISMUTH SUBSALICYLATE	262 mg in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARAMEL (UNII: T9D99G2B1R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

SODIUM SALICYLATE (UNII: WIQ1H85SYP)	
SORBIC ACID (UNII: X045WJ989B)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	VANILLA	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-2298-1	236 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	05/12/2008	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 1/2012 Physicians Total Care, Inc.