

KAOPECTATE- bismuth subsalicylate tablet
Chattem, 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 Caplets

Kaopectate

Active ingredient (per caplet)

Bismuth subsalicylate 262 mg

Purpose

Anti-diarrheal, Upset stomach reliever

Uses

- relieves diarrhea
- relieves travelers' 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

- anticoagulation (thinning the blood)
- diabetes

- gout
- arthritis

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

- adults and children 12 years of age and older: 2 caplets
- swallow caplets with water; do not chew
- repeat does 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 caplet contains: **total salicylates 99 mg**
- **do not use if carton was opened or if printed foil inner seal under bottle cap is torn or missing**
- store at room temperature 20°-25°C (68°-77° F)

Inactive Ingredients

croscarmellose sodium, crospovidone, hydrated silica, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, pharmaceutical ink, povidone, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin (309-034)

Distributed by:

Chattem, Inc.

P.O. Box 2219

Chattanooga, TN

37409-0219

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Principal Display Panel

Bismuth Subsalicylate

Kaopectate®

- **Multi-Symptom Relief**

- Anti-Diarrheal
- Upset Stomach Reliever

Relieves 7 types of Stomach Ailments:

- Diarrhea
- Upset Stomach
- Nausea
- Gas
- Heartburn
- Travelers " Diarrhea
- Indgestion

28 Coated Caplets



l.cartlan
com

- Nausea
- Heartburn
- Indigestion
- Gas
- Travelers' Diarrhea

28 Coated Caplets

ACTUAL SIZE

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Drug Facts (continued)

• 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

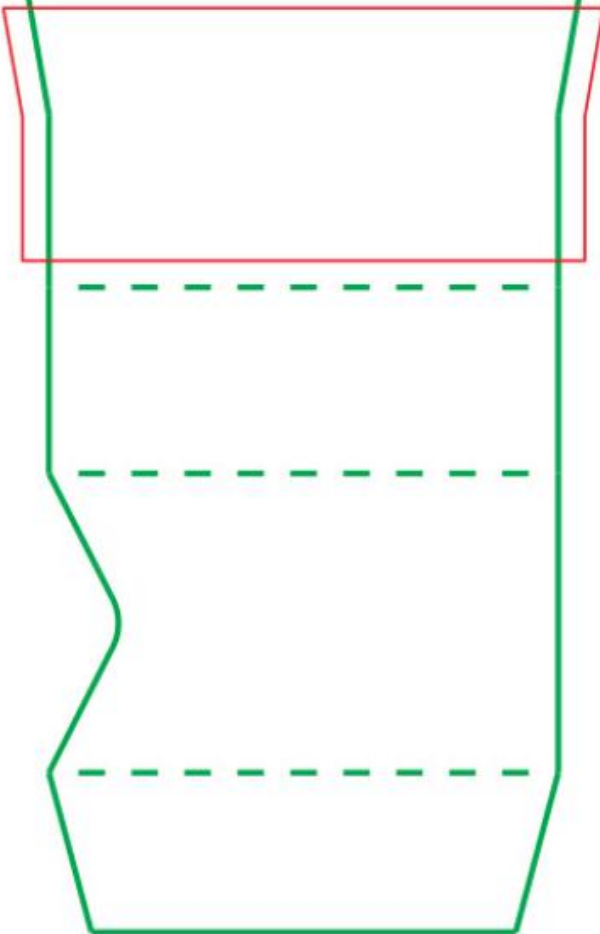
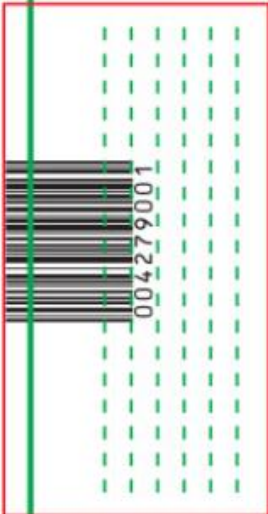
- adults and children 12 years of age and older: 2 caplets
- swallow caplets with water; do not chew
- repeat dose every 12 hour to 1 hour as needed
- do not exceed 8 doses in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- each caplet contains: total salicylates 59 mg
- do not use if carton was opened or if printed foil inner seal under bottle cap is torn or missing
- store at room temperature 20°-25° C (68°-77° F)

Inactive ingredients

croscarmellose sodium, crospovidone, hydrated silica, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, pharmaceutical ink, povidone, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin (09-034)



KAOPECTATE

bismuth subsalicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-4002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL (caplet)	Size	17mm
Flavor		Imprint Code	Kaopectate
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-4002-5	1 in 1 CARTON	04/01/2013	
1		28 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	04/01/2013	

Labeler - Chattem, Inc. (003336013)

Revised: 4/2013

Chattem, Inc.