

**KAOPECTATE- bismuth subsalicylate tablet, coated**  
**Kramer Laboratories**

*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.*

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**Drug Facts**

<b>Active ingredient (per caplet)</b>	<b>Purposes</b>
Bismuth subsalicylate 262 mg	Anti-diarrheal, Upset stomach reliever

**Uses** relieves:

- traveler's diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
  - heartburn
  - indigestion
  - nausea
  - gas
  - belching
  - fullness

**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 (1 dose)
- swallow caplets with water; do not chew
- 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 caplet contains very low sodium
- **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, povidone, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin

**Principal Display Panel**

***FAST & EFFECTIVE RELIEF***

**Kaopectate®**

*Bismuth Subsalicylate*

• *Anti-Diarrheal • Upset Stomach Reliever*

**Diarrhea &  
Upset Stomach**

- ☐ Begins controlling symptoms from the first dose
- ☐ Quickly relieves urgency, gas, and cramping

□ Effective on diarrhea from bacteria, viruses, and other causes

CLINICALLY PROVEN MEDICINE

28 Coated Caplets



**LOT**

**EXP**

**Do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken.**

**Kramer Laboratories, Inc.**  
Bridgewater, NJ 08807  
**1-800-824-4894**

14711-07-20\_K0720

# Kaopectate<sup>®</sup>

**Bismuth Subsalicylate**  
• Anti-Diarrheal • Upset Stomach Reliever

## Drug Facts

**Active ingredient (per caplet)** Bismuth subsalicylate 262 mg.....**Purposes** Anti-diarrheal, Upset stomach reliever

**Uses** relieves: • traveler's diarrhea • diarrhea • upset stomach due to overindulgence in food and drink, including: • heartburn • indigestion • nausea • gas • belching • fullness

### 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

## Drug Facts (continued)

**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.

## Drug Facts (continued)

### Directions

- adults and children 12 years of age and older: 2 caplets (1 dose)
- swallow caplets with water; do not chew
- 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
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### Other information

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## Drug Facts (continued)

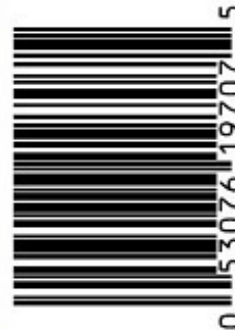
### Inactive ingredients

croscarmellose sodium, crospovidone, hydrated silica, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, povidone, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin

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LOT  
EXP



**Kaopectate®**

**Bismuth Subsalicylate**

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

**Diarrhea & Upset Stomach**

**28 Coated Caplets**

**Do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken.**

**KEEP CARTON AS IT CONTAINS IMPORTANT INFORMATION**

**Kramer Laboratories, Inc.**

Bridgewater, NJ 08807

**1-800-824-4894**

14712-07-20\_K0720



**Active ingredient** (in each caplet)  
Bismuth subsalicylate 262 mg

**Purposes** Anti-diarrheal, Upset stomach  
reliever **Uses relieves:** • traveler's  
diarrhea • diarrhea • upset stomach  
due to overindulgence in food and drink,  
including: • heartburn • indigestion •  
nausea • gas • belching • fullness

**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 •

**PEEL HERE ▼**

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 (1 dose)  
• swallow caplets with water; do not chew  
• 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 caplet contains

Continued ▼

very low sodium • **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,  
povidone, sodium lauryl sulfate, stearic  
acid, talc, titanium dioxide, triacetin

**Do not use if foil seal under  
cap, printed with "SEALED for  
YOUR PROTECTION"  
is missing, open or broken.**

**KEEP CARTON AS IT CONTAINS  
IMPORTANT INFORMATION**

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Bridgewater, NJ 08807  
1-800-824-4894

14712-07-20\_K0720

# KAOPECTATE

bismuth subsalicylate tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55505-197
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Bismuth Subsalsicylate (UNII: 62TEY51RR1) (Bismuth Cation - UNII:ZS9CD1I8YE)	Bismuth Subsalsicylate	262 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
Croscarmellose Sodium (UNII: M28OL1HH48)	
Crospovidone (UNII: 2S7830E561)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Mineral Oil (UNII: T5L8T28FGP)	
Povidone, Unspecified (UNII: FZ989GH94E)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Talc (UNII: 7SEV7J4R1U)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Triacetin (UNII: XHX3C3X673)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL (caplet)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	K
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55505-197-07	1 in 1 CARTON	10/01/2020	
1		28 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55505-197-70	1 in 1 CARTON	02/01/2021	
2		42 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC MONOGRAPH FINAL	part335	10/01/2020	
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**Labeler** - Kramer Laboratories (122720675)

**Establishment**

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corporation		057795122	manufacture(55505-197)

Revised: 1/2021

Kramer Laboratories