# KA PEC - bismuth subsalicylate liquid Rij Pharmaceutical Corporation

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**

# Active ingredient (in each tables poon= 15 mL)

Bismuth subsalicylate 262 mg

# **Purpose**

Anti-diarrheal

#### Uses

- controls diarrhea
- reduce number of bowel movements
- help firm stool

# **Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from children 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 bloody or black stool
- if you have an ulcer or bleeding problem

### Ask a doctor before use if you have

- fever
- mucus in the stool
- a magnesium-restricted diet
- a sodium-restricted diet

# 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

- Drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- shake well before using
- repeat dosage every 1/2 to 1 hour as needed
- do not take more than 8 doses in 24 hours
- use until diarrhea stops but not more than 2 days
- adults & children 12 years and over: 2 tablespoons (30 mL)
- children under 12 years: ask a doctor

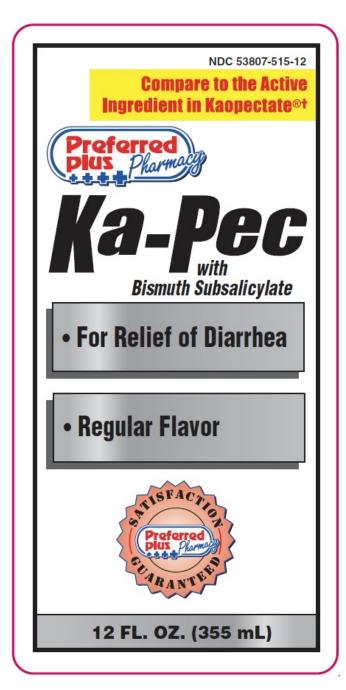
# **Inactive ingredients**

Carboxymethylcellulose sodium, flavor, glycerin, magnesium aluminum silicate, saccharin sodium, salicylic acid, sodium benzoate, sodium saliycylate, sorbitol, water

#### Other information

- Store at room temperature. Protect from freezing and excessive heat (over 40°C or 104°F)
- each tablespoon (15 mL) contains: magnesium 32 mg
- each tables poon (15 mL) contains: sodium 24 mg
- TAMPER EVIDENT: DO NOT USE IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING.

# **Principal Display Panel**



#### KA-PEC

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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

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†This product is not manufactured or distributed by the owner of the registered trademark of Kaopectate<sup>(8)</sup>

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Manufactured By: RIJ Pharmaceutical Corp. 40 Commercial Avenue Middletown, NY 10941

Distributed By: Kinray Inc., Whitestone, NY 11357



### KA PEC

bismuth subsalicylate liquid

### **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source) NDC:53807-515

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD118YE)	BISMUTH SUBSALICYLATE	262 mg in 15 mL

Inactive Ingredients	
Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM SALICYLATE (UNII: WIQ 1H8 5 S YP)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:53807-515-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part335	03/16/1999		

# Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rij Pharmaceutical Corporation		144679156	manufacture(53807-515)	

Revised: 4/2018 Rij Pharmaceutical Corporation