RAPIDOL STOMACH RELIEF- bismuth subsalicylate liquid
Pharmadel LLC

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.

Rapidol Stomach Relief (APTA)

Drug Facts

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Active ingredient & Purposes

Active ingredient (in each 30 mL dose cup or 2 tablespoons)	***Purposes***
Bismuth subsalicylate 525 mg.....	Upset stomach reliever and antidiarrhea

Uses

relieves
- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence of food and drink including:
- heart burn
- indigestion
- nausea
- gas
- belching

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
- black or bloody stool

Ask a doctor before use if you have

- fever
- mucus in stool

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

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

When using this product

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

Slop use and ask a doctor if

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

If pregnant or breast feeding,

ask 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 before use**
- **use dose cup or tablespoon (TBSP)**
- **adults and children 12 years and over:** 1 dose (30 mL or 2 TBSP) every 1/2 to 1 hour or every hour as needed
- do not exceed 8 doses (240 mL or 16 TBSP) in 24 hours
- use until diarrhea stops but not more than 2 days
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- **children under 12 years:** ask adoctor

Other information

- **each 30 mL dose contains:** magnesium45 mg, sodium 13 mg, salicylate 256 mg
- protect from freezing
- avoid excessive heat (over 104ºF or 40ºC)
- low sodium

Inactive ingredients

benzoic acid, D&C red #22, D&C red #28, flavor, purified water, saccharin sodium, salicylic acid, sodium salicylate, xanthan gum

Questions?

1-866-359-3478 (9 AM - 5 PM EST) or pharmadel.com

Distributed by:

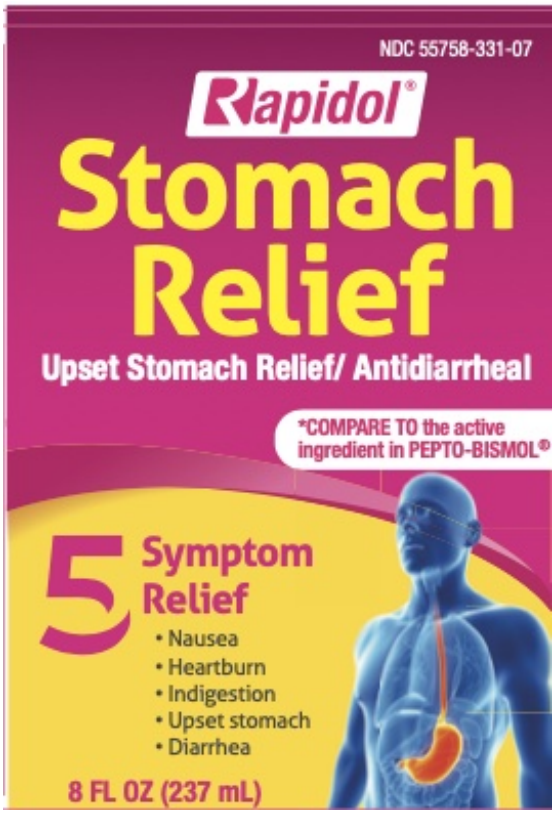
PHARMADEL LLC.

New Castle, DE 19720

Prinicpal Display Panel

NDC 55758-331-07

Rapidol Stomach Relief 8 FL OZ (237 mL)



RAPIDOL STOMACH RELIEF

bismuth subsalicylate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-331
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM SALICYLATE (UNII: WQ1H85SYP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	pink (color suspension)	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-331-08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2022	12/08/2022
2	NDC:55758-331-07	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	12/08/2022	

Labeler - Pharmadel LLC (030129680)

Revised: 2/2023 Pharmadel LLC