

UPSET STOMACH RELIEF TO GO- bismuth subsalicylate powder
Breakthrough Products 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.

Upset Stomach Relief to Go™

Drug Facts

Active ingredient (per powder)

Bismuth subsalicylate 525mg

Purpose

Upset stomach reliever/antidiarrheal

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 chickenpox 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 or last more than 2 days
- ringing in the ears or loss of hearing occurs
- diarrhea lasts for 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 and over:**

- see instructions in red box for opening packet
- place 1 powder on the tongue and swallow with or without water every ½ to 1 hour as needed
- do not exceed 8 doses 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 a doctor**Other information**

each dose contains salicylate 199mg

Inactive ingredients

citric acid, flavor, glucose, silica, sucralose

Questions?

1-888-998-7436 (Mon-Fri 9AM-5PM MDT)

Do not use if pouch is torn or open
--

distributed by

URGENT Rx®

Breakthrough Products, Inc.

Denver, CO 80202

PRINCIPAL DISPLAY PANEL - 1 Powder Packet

New!

**NO
WATER
REQUIRED**
POUR DIRECTLY IN MOUTH

**URGENT Rx[®]
FAST
POWDERS[™]**

▣ SEE OPENING INSTRUCTIONS ON BACK PANEL ▣

**UPSET
STOMACH**

URGENT Rx[®]

**RELIEF
TO-GO[™]**

BISMUTH SUBSALICYLATE/
UPSET STOMACH RELIEVER & ANTIDIARRHEAL

cherry

distributed by UrgentRx
1 POWDER PACK

New!

NO WATER
POUR

Do not use if pouch
is torn or open

Upset Stomach Relief to Go™

distributed by

URGENT Rx®

Breakthrough Products, Inc.

Denver, CO 80202

Fold top and store in purse or wallet

US Pat. No 8,376,140

CCUS074-A



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Drug Facts

Active ingredient (per powder)

Bismuth subsalicylate 525mg Upset stomach reliever/antidiarrheal

Uses Relieves: • traveler's diarrhea • diarrhea • upset stomach due

to overindulgence in food and drink, including: • heartburn

• indigestion • nausea • gas • belching • fullness

Warnings Children and teenagers who have or are

recovering from chickenpox 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 or last more than 2 days • ringing in the ears or loss of hearing

occurs • diarrhea lasts for more than 2 days If pregnant or breast-feeding, ask a

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medical help or contact a Poison Control Center right away. Directions adults and

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powder on the tongue and swallow with or without water every ½ to 1 hour as needed •

do not exceed 8 doses 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 a doctor Other information each dose contains salicylate

199mg inactive ingredients citric acid, flavor, glucose, silica, sucralose

Questions? 1-888-998-7436 (Mon-Fri 9AM-5PM MDT)

TO OPEN

- 1) FOLD ON LINE TO EXPOSE NOTCH
- 2) WHILE FOLDED, TEAR AT NOTCH

(or use scissors)

WATER
REQUIRED
DIRECTLY IN MOUTH

URGENT Rx[®]
FAST
POWDERS™

◀ SEE OPENING INSTRUCTIONS ON BACK PANEL ▶

**UPSET
STOMACH**



**RELIEF
TO-GO™**

BISMUTH SUBSALICYLATE/
UPSET STOMACH RELIEVER & ANTIDIARRHEAL

cherry

distributed by UrgentRx

1 POWDER PACK

UPSET STOMACH RELIEF TO GO

bismuth subsalicylate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51596-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Bismuth subsalicylate (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH CATION - UNII:ZS9CD1I8YE)	Bismuth subsalicylate	525 mg

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
dextrose (UNII: IY9XDZ35W2)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51596-004-05	5 in 1 BOX		
1	NDC:51596-004-01	1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:51596-004-12	12 in 1 BOX		
2	NDC:51596-004-01	1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:51596-004-24	24 in 1 BOX		
3	NDC:51596-004-01	1 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:51596-004-10	10 in 1 BOX		
4		1 in 1 PACKET; 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	09/01/2011	

Labeler - Breakthrough Products Inc. (962008251)