

EQUALINE STOMACH RELIEF- bismuth subsalicylate suspension **Supervalu 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.

SuperValu Inc. Stomach Relief Drug Facts

Active ingredient (in each 30 mL dose cup)

Bismuth subsalicylate 1050 mg

Purposes

Upset stomach reliever and antidiarrheal

Uses

relieves

- travelers' 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

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

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. (1-800-222-1222)

Directions

- shake well before use
- use dose cup
- adults and children 12 years and over: 1 dose (30 mL or 2 TBSP) every hour as needed
- do not exceed 4 doses (120 mL or 8 TBSP) 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 30 mL dose cup contains: magnesium 15 mg, potassium 5 mg and sodium 12 mg
- salicylate 461 mg
- low sodium
- protect from freezing
- does not meet USP requirements for pH
- for health information visit www.more-info.info

Inactive ingredients

D&C red #22, D&C red #28, magnesium aluminum silicate, methyl salicylate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid, xanthan gum

Questions or comments?

1-877-932-7948

Principal Display Panel

compare to Pepto-Bismol® Max Strength active ingredient

maximum strength

stomach relief liquid

bismuth subsalicylate

1050mg per 30mL

(upset stomach reliever/anti-diarrheal)

5 symptom digestive relief

heartburn

indigestion

nausea

upset stomach

diarrhea

8 FL OZ (237mL)

<p>Drug Facts (continued) Store at 20-25°C (68-77°F).</p> <ul style="list-style-type: none">■ ringing in the ears or loss of hearing occurs■ diarrhea lasts more than 2 days <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)</p> <p>Directions ■ shake well before use ■ use dose cup</p> <ul style="list-style-type: none">■ adults and children 12 years and over: 1 dose (30 mL or 2 TBSP) every hour as needed■ do not exceed 4 doses (120 mL or 8 TBSP) 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 <p>Other information ■ each 30 mL dose cup contains: magnesium 15 mg, potassium 5 mg and sodium 12 mg</p> <ul style="list-style-type: none">■ salicylate 461 mg ■ low sodium ■ protect from freezing■ does not meet USP requirements for pH■ for health information visit www.more-info.info <p>Inactive ingredients D&C red #22, D&C red #28, magnesium aluminum silicate, methyl salicylate, methylcellulose, purified water, saccharin sodium, salicylic acid, sodium salicylate, sorbic acid, xanthan gum</p> <p>Questions or comments? 1-877-932-7948</p>	<p>NDC 41163-600-34</p> <p>compare to Pepto-Bismol® Max Strength active ingredient*</p> <p>EQUALINE®</p> <p>maximum strength stomach relief liquid</p> <p>bismuth subsalicylate 1050mg per 30mL (upset stomach reliever/ anti-diarrheal)</p> <p>5 symptom digestive relief</p> <ul style="list-style-type: none">• heartburn• indigestion• nausea• upset stomach• diarrhea <p>8 FL OZ (237mL)</p>	<p>Drug Facts DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING</p> <table border="1"><thead><tr><th>Active ingredient (in each 30 mL dose cup)</th><th>Purposes</th></tr></thead><tbody><tr><td>Bismuth subsalicylate 1050 mg.....</td><td>Upset stomach reliever and antidiarrheal</td></tr></tbody></table> <p>Uses relieves ■ travelers' diarrhea ■ diarrhea</p> <ul style="list-style-type: none">■ upset stomach due to overindulgence in food and drink, including: ■ heartburn ■ indigestion ■ nausea■ gas ■ belching ■ fullness <p>Warnings</p> <p>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.</p> <p>Allergy alert: Contains salicylate. Do not take if you are</p> <ul style="list-style-type: none">■ allergic to salicylates (including aspirin)■ taking other salicylate products <p>Do not use if you have</p> <ul style="list-style-type: none">■ an ulcer■ a bleeding problem ■ bloody or black stool <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none">■ fever ■ mucus in the stool <p>Ask a doctor or pharmacist before use if you are taking any drug for</p> <ul style="list-style-type: none">■ anticoagulation (thinning the blood)■ diabetes ■ gout ■ arthritis <p>When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none">■ symptoms get worse	Active ingredient (in each 30 mL dose cup)	Purposes	Bismuth subsalicylate 1050 mg.....	Upset stomach reliever and antidiarrheal
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Bismuth subsalicylate 1050 mg.....	Upset stomach reliever and antidiarrheal					

EQUALINE STOMACH RELIEF

bismuth subsalicylate suspension

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41163-600
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (SALICYLIC ACID and BISMUTH CATION)	BISMUTH SUBSALICYLATE	1050 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 22	
D&C RED NO. 28	
MAGNESIUM ALUMINUM SILICATE	
METHYL SALICYLATE	
WATER	
SACCHARIN SODIUM	
SALICYLIC ACID	
SODIUM SALICYLATE	
SORBIC ACID	
XANTHAN GUM	

Product Characteristics

Color	PINK (viscous)	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-600-34	237 mL in 1 BOTTLE		
2	NDC:41163-600-40	355 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph final	part335	10/07/2004	

Labeler - Supervalu Inc (006961411)