STOMACH RELIEF- bismuth subsalicylate tablet, chewable SDA Laboratories, 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.

Drug Facts

Active Ingredient (in each tablet)

Bismuth subsalicylate 262mg

Purposes

Anti-diarrheal/ Upset stomach reliever

Uses

- controls diarrhea
- relieves upset stomach due to overindulgence in food or drink

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 symtoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: 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

Ask a doctor or pharmacist before use if you are

talking 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
- repeat dosage every 1/2 to 1 hour as needed
- do not take more than 8 doses in 24 hours
- use untill diarrhea stops but not more than 2 days
- adults and children 12 years and over: 2 tablets
- children under 12 years: ask a doctor

Other information

- each tablet contains: calcium 77 mg, salicylate 102 mg
- store at 15 to 30⁰ C (59 to 86⁰ F)
- protect from moisture

Inactive ingredients

calcium carbonate, D&C red #27(Al-lake), dextrose, flavor(cherry), magnesium stearate, maltodextrin, silicon dioxide, sorbitol

Questions or comments?

Adverse drug event call 1-(714)-903-7952

Principal Display Panel

NDC 66424-045-30

Stomach Relief

Bismuth Subsalicylate 262 mg

Anti-Diarrheal/ Upset Stomach Reliever

Helps to Relieve:

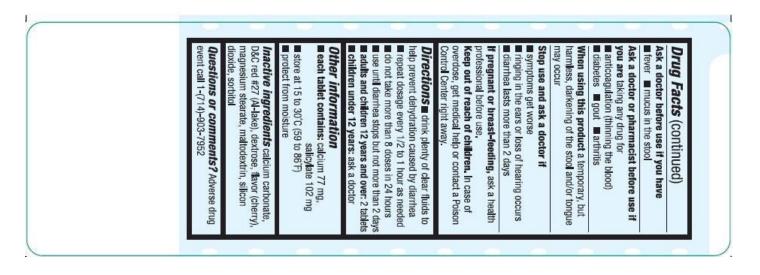
- Upset Stomach
- Diarrhea
- Indigestion
- Heartburn
- Nausea

[†]Compare to the Active Ingredients in Pepto-Bismol

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

†This product is not manufactured or distributed by Proctor & Gamble, owner of the registered trademark Pepto-Bismol





STOMACH RELIEF

bismuth subsalicylate tablet, chewable

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Sourc	ze)	NDC:66424-0	45
Route of Administration	ORAL				
Active Ingredient/Active Moi	ety				
Ingredient Name Basis of S				Strength	Strengt
BISMUTH SUBSALICYLATE (UNII: 62	TEY51RR1) (BISMUTH CATION	- UNII:ZS9CD1I8YE)	BISMUTH SUE	SALICYLATE	262 mg
Inactive Ingredients					
Ingredient Name				Strength	
CALCIUM CARBONATE (UNII: H0 G9 3	79FGK)				
D&C RED NO.27 (UNII: 2LRS185U6K)					
DEXTROSE (UNII: IY9XDZ35W2)					
MAGNESIUM STEARATE (UNII: 7009	7M6I30)				

MALTO DEXTRIN (UNII	: 7CVR7L4A2D)						
SILICON DIO XIDE (UN	II: ETJ7Z6XBU4)						
SORBITOL (UNII: 506T	60A25R)						
Product Character	ristics						
Color	pink (light)	Score		no score			
Shape	ROUND	Size		16 mm			
Flavor	CHERRY	Imprint Code		AP;045			
Contains							
Packaging							
# Item Code	Package Description	Marketi	ng Start Date	Μ	larketing End Date		
1 NDC:66424-045-30	30 in 1 BOTTLE, PLASTIC						
Marketing Information							
Marketing Category	Application Number or Mono	Application Number or Monograph Citation		Date	Marketing End Date		
OTC monograph final	part335		09/27/2012				

Labeler - SDA Laboratories, Inc. (948067889)

Revised: 8/2013

SDA Laboratories, Inc.