BISMUTH SUBSALICYLATE 262 MG- bismuth subsalicylate tablet, chewable Reliable 1 Laboratories 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.

Bismuth Subsalicylate 262 mg

Drug Facts

Active ingredient (in each tablet)

Bismuth subsalicylate 262 mg

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

Allergy alert: Contains salicylates. 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

Drug Facts continued on back of label

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 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 until 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°-30°C (59°-86°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?

call 516-341-0666, 8:30 am- 4:30 pm ET, Monday-Friday

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

*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark Pepto-Bismol®

Distributed by: Reliable 1 Laboratories LLC, Valley Stream, NY 11580

www.reliable1labs.com

NDC 69618-029-03

Bismuth Subsalicylate

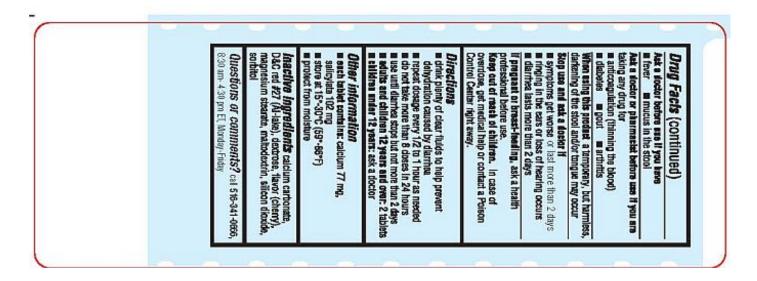
262 mg

UPSET STOMACH RELIEVER / ANTIDIARRHEAL

30 CHEWABLE TABLETS

*compare to Active Ingredients in Pepto-Bismol®





BISMUTH SUBSALICYLATE 262 MG

bismuth subsalicylate tablet, chewable

Product Information										
Product Type	HUMAN OTC DRUG Item Code (Source)			NDC:69618-029						
Route of Administration	ORAL									
Active Ingredient/Active Moiety										
Acuve ingredient/Acuve molecy										
I	ngredient Name		Basis	of Strength	Strength					
BISMUTH SUBSALICYLATE (UNII: 62' SALICYLIC ACID - UNII:0414PZ4LPZ)	BISMUTH SUBSALICYLATE 262 mg		262 mg							
Inactive Ingredients										
Inactive Ingredients										

C	ALCIUM CARBONA	TE (UNII: H0G9379FGK)								
D	DEXTROSE (UNII: IY9XDZ35W2)									
C	CHERRY (UNII: BUC519595W)									
Μ	MAGNESIUM STEARATE (UNII: 70097M6I30)									
Μ	MALTO DEXTRIN (UNII: 7CVR7L4A2D)									
D	D&C RED NO. 27 (UNII: 2LRS185U6K)									
SI	SILICON DIO XIDE (UNII: ETJ7Z6XBU4)									
s	SORBITOL (UNII: 506T60A25R)									
Product Characteristics										
C	olor	pink	Score	no	o score					
SI	hape	ROUND	Size	16	6 mm					
Fl	avor	CHERRY	Imprint Code	AP	AP;045					
С	ontains									
Р	ackaging									
#	Item Code	Package Description		Marketing Start Date	Marketing End Date					
1	NDC:69618-029- 03	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		11/0 1/20 15						



BISMUTH SUBSALICYLATE 262mg CHEW TABLET

Marketing Information

Marketing Category
OTC monograph final

y Application Number or Monograph Citation
part335

on Marketing Start Date

Marketing End Date

Labeler - Reliable 1 Laboratories LLC (079718111)

Revised: 12/2019

Reliable 1 Laboratories LLC