

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 Subsalsicylate 262 mg

Drug Facts

Active ingredient (in each tablet)

Bismuth subsalsicylate 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

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NDC 69618-029-03

Bismuth Subsalicylate

262 mg

UPSET STOMACH RELIEVER / ANTIDIARRHEAL

30 CHEWABLE TABLETS

*compare to Active Ingredients in Pepto-Bismol®

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Rev. 0815

3 69618 02903 3

Lot No.:

Exp. Date:

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-029
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
DEXTROSE (UNII: IY9XDZ35W2)	
CHERRY (UNII: BUC5I9595W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	16mm
Flavor	CHERRY	Imprint Code	AP;045
Contains			

Packaging

#	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	11/01/2015	



BISMUTH SUBSALICYLATE 262mg CHEW TABLET

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	11/01/2015	

Labeler - Reliable 1 Laboratories LLC (079718111)

Registrant - Reliable 1 Laboratories LLC (079718111)

Revised: 3/2023

Reliable 1 Laboratories LLC