PEPTO RELIEF- bismuth subsalicylate tablet, chewable
Richmond Pharmaceuticals, 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.

PEPTO RELIEF Bismuth Subsalicylate 262 MG

Drug Facts

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Active Ingredient

(in each tablet)

Bismuth subsalicylate 262 mg

Purpose

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: 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

- 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

- 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 INGREDIENT

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

Questions or Comments

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

Call 804-270-4498, 8.30 am – 4.30 pm EST Monday - Friday

Package Label

NDC: 54738-102-30

– 30 TABLETS

NDC: 54738-102-48- 48 TABLETS

PEPTO RELIEF

bismuth subsalicylate tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54738-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DEXTROSE (UNII: IY9XDZ35W2)	
CHERRY (UNII: BUC5I9595W)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	pink (light)	**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:54738-102-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2015	
2	NDC:54738-102-48	48 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	06/01/2015	

Labeler - Richmond Pharmaceuticals, Inc (043569607)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-102)

Revised: 10/2017 Richmond Pharmaceuticals, Inc