HEB STOMACH RELIEF CHERRY - bismuth subsalicylate tablet, chewable H E B

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.

HEB Stomach Relief Cherry

ACTIVE INGREDIENT(in each tablet)

Bismuth subsalicylate 262 mg (total salicylate 102 mg per tablet)

PURPOSE

Upset stomach reliever and anti-diarrheal

USE(S)

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

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 behaviour 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

- bloody or black stool
- an ulcer
- a 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 of 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 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

- chew or dissolve in mouth
- adults and children 12 years and over: 2 tablets every 1/2 to 1 hour as needed
- do not take more than 8 doses (16 tablets) in 24 hours
- children under 12 years: ask a doctor
- drink plenty of fluids to help prevent dehydration caused by diarrhea

OTHER INFORMATION

- each tablet contains:
- sodium less than 1 mg
- salicylate 102 mg
- very low sodium
- avoid excessive heat (over 104°F or 40°C)
- TAMPER EVIDENT: Do not use if individual compartments are torn or open

INACTIVE INGREDIENTS

adipic acid, calcium carbonate, D&C red 27 aluminum lake, FD&C red 40 aluminum lake, flavors, magnesium stearate, mannitol, povidone, pregelatinized starch, saccharin sodium

PRINCIPAL DISPLAY PANEL

Compate to Pepto-Bismol® Chewable active ingredient* NDC 37808-148-77

HEB

Stomach Relief

Bismuth Subsalicylate, 262 mg Upset Stomach Reliever/Antidiarrheal

Multi-Symptom Relief Relief of:

- Nausea
- Heartburn
- Indigestion
- Upset stomach
- Diarrhea

Cherry Flavor 30 CHEWABLE TABLETS



bismuth subsalicylate tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-148	
Route of Administration	ORAL			

Active Ingredient/Active Moiety Ingredient Name Basis of Strength BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:0414PZ4LPZ) BISMUTH SUBSALICYLATE (262 mg

Inactive Ingredients	
Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
D&C RED NO. 27 (UNII: 2LRS 185U6K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
ADIPIC ACID (UNII: 76 A0 JE0 FKJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics				
Color	PINK	Score	no score	
Shape	ROUND	Size	17mm	
Flavor	CHERRY	Imprint Code	GDC122	
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:37808-148-77	5 in 1 BOX	09/28/2018		
1	6 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part335	09/28/2018	

Labeler - HEB (007924756)

Revised: 9/2018 HE B