PEPT-ACHE- bismuth subsalicylate tablet, chewable JHK Inc dba American Safety & First Aid

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.

PEPT-ACHE

Drug Facts

Active ingredient (In Each Tablet)

Bismuth subsalicylate 262 mg (each tablet contains 102 mg salicylate)

Purpose

Antidiarrheal/Antacid

Use

temporarily relieves:

- controls diarrhea
- relieves heartburn, indigestion, nausea and upset stomach without constipating

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 Warning

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 a prescription drug for:

- anticoagulation (thinning of the blood)
- diabetes
- gout
- arthritis

Stop use and ask a doctor if

- symptoms get worse
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than two days

When using this product: a temporary, but harmless darkening of the stool and/or tongue may occur.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center right away.

Directions

- do not use more than directed
- chew or dissolve in mouth
- use until diarrhea stops but not more than 2 days
- drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea
- do not exceed 16 tablets in 24 hours Adults and children: (12 years and older) Chew
 2 tablets every 1/2 to 1 hour or 4 tablets every hour as needed

Children under 12 years: ask a doctor

Other information

- phenylketonurics: contains phenylalanine 1.1mg per tablet
- each tablet contains 73mg elemental calcium
- store at room temperature 59º-86ºF (15º-30ºC)
- tamper-evident sealed packets do not use if packet is opened or torn

Inactive ingredients

acacia gum, aspartame, calcium carbonate, D&C red #27, dextrates, flavoring, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide

Questions?

1-866-651-3660 Monday-Friday 8:00am-5:00pm EST

PRINCIPAL DISPLAY PANEL - 36 Tablet Packet Box

This product is not manufactured or distributed by Proctor & Gamble Owner of the registered trademark Pepto-Bismol[®].

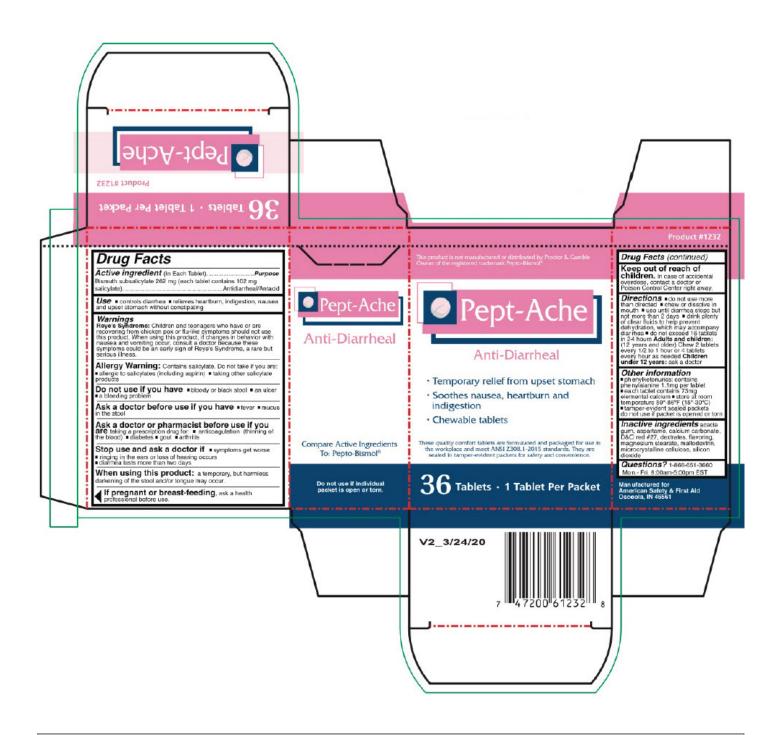
Pept-Ache

Anti-Diarrheal

- Temporary relief from upset stomach
- Soothes nausea, heartburn and indigestion
- Chewable tablets

These quality comfort tablets are formulated and packaged for use in the workplace and meet ANSI Z308. 1-2015 standards. They are sealed in tamper-evident packets for safety and convenience.

36 Tablets • 1 Tablet Per Packet



PEPT-ACHE

bismuth subsalicylate tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73598-1232	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII: O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg	

Inactive Ingredients			
Ingredient Name	Strength		
ACACIA (UNII: 5C5403N26O)			
ASPARTAME (UNII: Z0H242BBR1)			
CALCIUM CARBONATE (UNII: H0G9379FGK)			
D&C RED NO. 27 (UNII: 2LRS185U6K)			
DEXTRATES (UNII: G263MI44RU)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			

Product Characteristics			
Color	PINK	Score	no score
Shape	ROUND	Size	13mm
Flavor	PEPPERMINT	Imprint Code	RH046
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73598- 1232-1	36 in 1 BOX	02/02/2000		
1		1 in 1 PACKET; 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	02/02/2000		

Labeler - JHK Inc dba American Safety & First Aid (867236309)

Revised: 9/2022 JHK Inc dba American Safety & First Aid