

CHEWABLE- bismuth subsalicylate tablet, chewable
Publix Super Markets 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.

Publix Super Markets, Inc. Chewable Drug Facts

Active ingredient (in each tablet)

Bismuth subsalicylate 262 mg

Purpose

Upset stomach reliever/antidiarrheal

Uses

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
- heartburn
- indigestion
- nausea
- gas
- belching
- fullness

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 salicylate. Do not take if you are

- allergic to salicylates (including aspirin)
- taking other salicylate products

Do not use

if you have

- an ulcer
- a bleeding problem
- bloody or black stool

Ask a doctor before use if you have

- fever
- mucus in the stool
- kidney stones
- a calcium-restricted diet

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. (1-800-222-1222)

Directions

- chew or dissolve tablets in mouth
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- adults and children 12 years and over: 2 tablets every ½ to 1 hour, or 4 tablets every hour as needed
- do not exceed 16 tablets in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor

Other information

- each tablet contains: calcium 265 mg and salicylate 99 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

calcium carbonate, D&C red #27 aluminum lake, FD&C blue #1 aluminum lake, flavor, magnesium stearate, mannitol, saccharin sodium

Principal Display Panel

STOMACH RELIEF

chewable

BISMUTH SUBSALICYLATE 262mg

ANTIDIARRHEAL

UPSET STOMACH RELIEVER

Soothing relief for:

heartburn

indigestion

upset stomach

nausea

diarrhea

ACTUAL SIZE

Compare to Active Ingredient in Pepto-Bismol® Chewable Tablets



CONVENIENT RECLOSING TAB



NDC 56062-469-65

TABLETS
PROTECTED BY
PRINTED INNER
WRAP. DO NOT
USE IF TORN
OR MISSING.

STOMACH RELIEF

chewable

BISMUTH SUBSALICYLATE 262mg

**ANTIDIARRHEAL
UPSET STOMACH RELIEVER**

Soothing relief for:

- heartburn
- indigestion
- upset stomach
- nausea
- diarrhea



ACTUAL SIZE

30 TABLETS

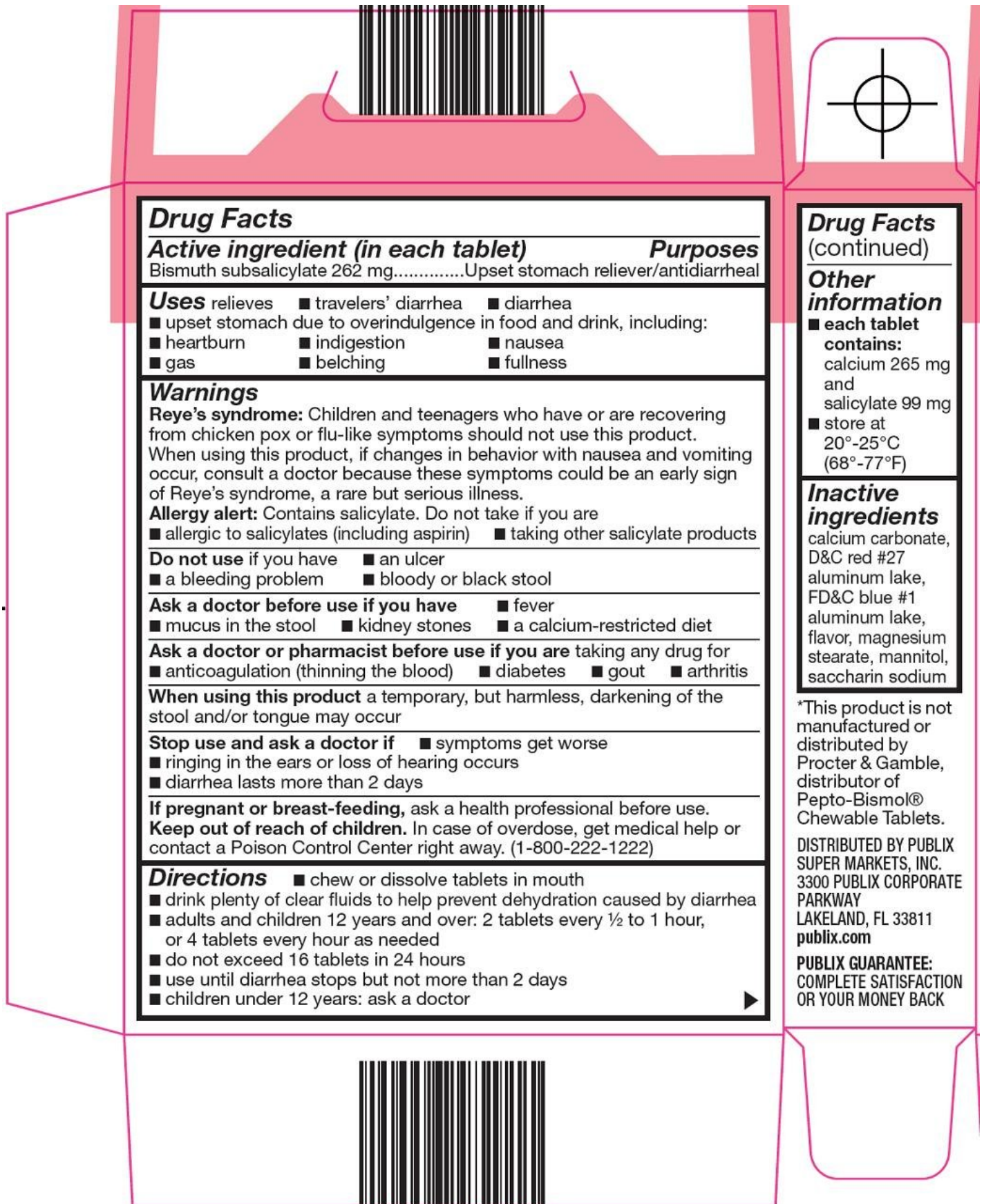
*Compare to Active Ingredient in
Pepto-Bismol® Chewable Tablets



OPEN OTHER END



Chewable Carton Image 1



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Drug Facts
(continued)

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*This product is not manufactured or distributed by Procter & Gamble, distributor of Pepto-Bismol® Chewable Tablets.

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 COMPLETE SATISFACTION OR YOUR MONEY BACK

Chewable Carton Image 2

CHEWABLE

bismuth subsalicylate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-469
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH SUBSALICYLATE - UNII:62TEY51RR1)	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	17mm
Flavor		Imprint Code	L469
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-469-65	5 in 1 CARTON		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	03/15/2001	

Labeler - Publix Super Markets Inc (006922009)