ANTI-DIARRHEAL MAXIMUM STRENGTH- bismuth subsalicylate tablet Wal-Mart Stores 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.

Equate 44-749

Active ingredient (in each caplet)

Bismuth subsalicylate 525 mg

Purpose

Antidiarrheal

Uses

relieves

- traveler's diarrhea
- diarrhea

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 chances 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

Ask a doctor or pharmacist before use if you are

taking any drug for

- anticoagulation (thinning the blood)
- gout
- diabetes
- 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
- swallow with water; do not chew
- adults and children 12 years and over: 1 caplet every 1/2 hour or 2 caplets every hour as needed
- do not exceed 8 caplets in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor

Other information

- each caplet contains: calcium 45 mg, salicylate 206 mg, sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive heat
- use by expiration date on package

Inactive ingredients

calcium carbonate, corn starch, D&C red #27 aluminum lake, D&C red #30 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Questions or comments?

1-888-287-1915

Principal display panel

equateTM

NDC 49035-769-08

Compare to the active ingredient in Pepto® Diarrhea*

MAXIMUM STRENGTH

Anti-Diarrheal

Bismuth subsalicylate 525 mg Anti-Diarrheal

Relieves Diarrhea

Actual Size

525 mg EACH

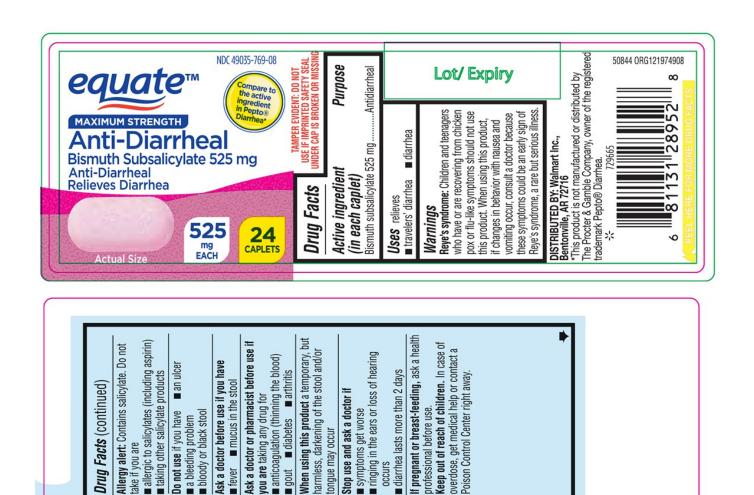
24 CAPLETS

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

DISTRIBUTED BY: Walmart inc., Bentonville, AR 72716

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Pepto® Diarrhea.

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tongue may occur

bloody or black stool a bleeding problem

take if you are

Equate 44-749

ANTI-DIARRHEAL MAXIMUM STRENGTH				
bismuth subsalicylate tablet				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-769	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
, ,	BISMUTH SUBSALICYLATE	525 mg		

Inactive Ingredients	
Ingredient Name	Strength
CALCIUM CARBO NATE (UNII: H0 G9 379 FGK)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
PO VIDO NE (UNII: FZ989 GH94E)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics				
Color	PINK	Score	no score	
Shape	OVAL	Size	19 mm	
Flavor		Imprint Code	44;749	
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-769-08	24 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part335	04/06/2020		

Labeler - Wal-Mart Stores Inc (051957769)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(49035-769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(49035-769)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(49035-769)

Revised: 3/2020 Wal-Mart Stores Inc