

## **STOMACH RELIEF REGULAR STRENGTH- bismuth subsalicylate liquid EQUATE (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.*

-----

### **Drug Facts**

#### **Active ingredient (in each 30 mL)**

Bismuth subsalicylate 525 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
  - fullness
  - belching

#### **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

#### **Ask a doctor or pharmacist before use if you are**

taking any drug for

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

### **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 or last more than 2 days
- 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**

- mL = milliliter
- shake well before using
- measure only with dosing cup provided. do not use any other dosing device.
- keep dosing cup with product
- adults and children 12 years and over
  - 30 mL (1 dose) every 1/2 or 60 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea
  - 30 mL (1 dose) every 1/2 as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
  - do not exceed 8 doses (240 mL) in 24 hours
  - use until diarrhea stops but not more than 2 days
- children under 12 years of age: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

### **Other information**

- **each 30 mL contains:** potassium 8 mg sodium 6 mg
- **each 30 mL contains:** salicylate 206 mg
- low sodium
- keep tightly closed
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)

### **Inactive ingredients**

benzoic acid, D&C red #22, D&C red #28, flavor, glycerin, purified water, sucralose, xanthan gum

### **Questions or comments?**

Call 1-888-287-1915

## Principal Display Panel

### NEW & IMPROVED FORMULA

Compare to the active ingredient in Pepto-Bismol®\*

### Regular Strength

Stomach Relief

Bismuth subsalicylate 525 mg

upset stomach reliever/antidiarrheal

Relieves

- Heartburn
- Indigestion
- Nausea
- Upset stomach
- Diarrhea

Alcohol free

Sugar free

FL OZ (mL)

\*This product is not manufactured or distributed by The Procter & Gamble Company. Pepto-Bismol® is a registered trademark of The Procter & Gamble Company.

**TAMPER EVIDENT; DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.**

**DISTRIBUTED BY: Wal-mart Inc.,**

**Bentonville, AR 72716**

## Package Label

**2 PACK**

**equate™** NEW & IMPROVED FORMULA

REGULAR STRENGTH

**Stomach Relief**

Bismuth Subsalsicylate 525mg

Upset Stomach Reliever/Antidiarrheal

Relieves

- Heartburn
- Indigestion
- Nausea
- Upset stomach
- Diarrhea

Alcohol-free  
Sugar-free

**525 mg** per 30mL

**2 BOTTLES**

2 - 16 FL OZ (1 PT) 473mL BOTTLES  
32 FL OZ (2 PT) 946mL TOTAL

**Drug Facts**

Active Ingredient (in each 30 mL dose)	Purpose
Bismuth subsalsicylate 525 mg	Upset stomach reliever/Antidiarrheal

**Warnings**

Pepto-Bismol: Children and teenagers who have an increasing 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.

**Always 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:**

- liver
- kidney
- stomach
- heart
- diabetes
- gout
- arthritis
- anticoagulation (thinning the blood)

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

**Stop use and ask a doctor if:**

- symptoms get worse or last more than 2 days
- 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 (1-800-222-1222) right away.**

**Directions**

- mix - mix with water
- shake well before using
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product.
- adults and children 12 years and over
- 30 mL (1 oz) every 15-30 min (1-2 doses) every hour as needed for diarrhea/heartburn's diarrhea
- 30 mL (1 oz) every 15-30 min as needed for upset stomach, heartburn, indigestion, nausea
- do not exceed 6 doses (180 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years of age: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

**Other information**

- each 30 mL contains: potassium 6 mg, sodium 6 mg
- each 30 mL contains: salicylate 200 mg
- low sodium
- keep tightly closed
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)

**Inactive ingredients:** benzoic acid, D&E-red #22, D&E-red #39, flavor, glycerin, purified water, sucralose, sorbitan gum

**Questions or comments?** 1-800-391-0915

## EQUATE Regular Strength Stomach Relief

## STOMACH RELIEF REGULAR STRENGTH

bismuth subsalsicylate liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49035-725
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 30 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
BENZOIC ACID (UNII: 8SKN0B0MIM)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-725-32	2 in 1 PACKAGE	02/01/2020	
1		473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:49035-725-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2020	
3	NDC:49035-725-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2020	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part335	02/01/2020	

**Labeler** - EQUATE (Wal-Mart Stores, Inc.) (051957769)

Revised: 5/2020

EQUATE (Wal-Mart Stores, Inc.)