

HEB DIARRHEA RELIEF VANILLA FLAVOR- bismuth subsalicylate suspension **HEB**

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.

H-E-B® Diarrheal Relief

Drug Facts

Active Ingredient (per 15 mL)

Bismuth Subsalicylate 262 mg

Purposes

Anti-diarrheal/Upset stomach reliever

Uses

relieves

- traveler's diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink
- heartburn
- indigestion
- nausea
- gas

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

- a sodium-restricted diet
- 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
- 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 at 1-800-222-1222.

Directions

- **shake well immediately before each use**
- **adults and children 12 years of age and older:** 30 ml or 2 tablespoonful
- for accurate dosing, use convenient pre-measured dose cup
- repeat dose every 1/2 hour to 1 hour as needed
- do not exceed 8 doses in 24 hours
- use until diarrhea stops but not more than 2 days
- **children under 12 years:** ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- each 15mL tablespoon contains: **sodium 10 mg**
- each 15mL tablespoon contains: **salicylate 130 mg**
- **do not use if printed inner seal is broken or missing**
- store at room temperature

Inactive ingredients

caramel, carboxymethylcellulose sodium, microcrystalline cellulose, natural and artificial flavor, potassium sorbate, salicylic acid, simethicone emulsion, sucralose, sucrose, water, xanthan gum

Questions or comments?

1-866-467-2748

Principal Display Panel

H-E-B®

NDC 37808-173-12

Compare to Kaopectate® active ingredient*

Diarrhea Relief

Bismuth Subsalicylate, 262 mg per 15 mL/

Antidiarrheal/Upset Stomach Reliever

Multi-Symptom Relief

Relief of 7 Types of Stomach Ailments

Vanilla Flavor

Contains Salicylates

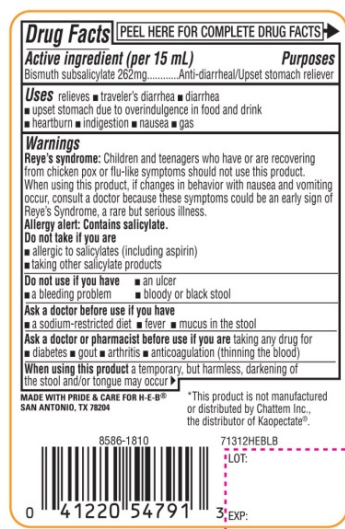
12 FL OZ (355 mL)

MADE WITH PRIDE & CARE FOR H-E-B® SAN ANTONIA, TX 78204

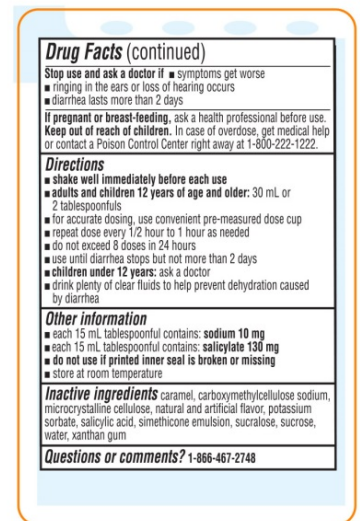
*This product is not manufactured or distributed by Chattem Inc., the distributor of Kaopectate®.



Front (1)



Back/Front (3)



Back/Back (4)

HEB DIARRHEA RELIEF VANILLA FLAVOR

bismuth subsalicylate suspension

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:37808-173 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|-----------------|
| Bismuth subsalicylate (UNII: 62TEY51RR1) (Salicylic acid - UNII:O414PZ4LPZ, Bismuth cation - UNII:ZS9CD1I8YE) | Bismuth subsalicylate | 262 mg in 15 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CARAMEL (UNII: T9D99G2B1R) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| salicylic acid (UNII: O414PZ4LPZ) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| SUCROSE (UNII: C151H8M554) | |
| WATER (UNII: 059QF0KO0R) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | VANILLA | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:37808-173-12 | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/14/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part335 | 05/14/2019 | |

