

WINCO FOODS ULTRA STRENGTH STOMACH RELIEF- bismuth subsalicylate suspension
WINCO FOODS

WinCo FOODS Ultra Strength Stomach Relief Drug Facts

Active ingredient (in each 15 mL dose)

Bismuth subsalicylate 525 mg

Purposes

Upset stomach reliever and 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 or 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)
- 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 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 at (1-800-222-1222).

Directions

- shake well before use
- only use dose cup provided
- **adults and children 12 years and over:** 15 mL (1 dose) every 1/2 or 30 mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea.
- 15 mL (1 dose) every 1/2 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (120 mL) 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 15 mL contains:** sodium 10 mg
- **salicylate 230 mg**
- low sodium
- sugar free
- store at room temperature
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients

carboxymethylcellulose sodium, D&C Red No. 22, D&C Red No. 28, flavor, microcrystalline cellulose, potassium hydroxide, potassium sorbate, purified water, salicylic acid, simethicone emulsion, sodium benzoate, sucralose, xanthan gum

Questions?

Call **800-824-1706 Monday - Friday 9am - 4pm MST**

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN.

Principal Display Panel

WinCo® FOODS

Compare to active ingredient PEPTO-BISMOL® Ultra Strength

ULTRA STRENGTH

Stomach Relief

BISMUTH SUBSALICYLATE

UPSET STOMACH RELIEVER & ANTI-DIARRHEAL

Soothing Relief for: Upset Stomach, Nausea, Heartburn & Diarrhea

DISTRIBUTED BY:

WINCO FOODS, LLC, BOISE, ID 83704

***This product is not manufactured or distributed by PROCTER & GAMBLE INC., distributor of PEPTO-BISMOL® Ultra Strength**

<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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.</p> <p>Directions ■ shake well before use ■ only use dose cup provided ■ adults and children 12 years and over ■ 15 mL (1 dose) every ½ hour or 30mL (2 doses) every hour as needed for diarrhea/traveler's diarrhea. ■ 15 mL (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea) ■ do not exceed 8 doses (120 mL) 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</p> <p>Other information ■ each 15 mL contains: sodium 10 mg ■ salicylate 230 mg ■ low sodium ■ sugar free ■ store at room temperature ■ protect from freezing ■ avoid excessive heat (over than 104°F or 40°C)</p> <p>Inactive ingredients carboxymethylcellulose sodium, D&C Red No. 22, D&C Red No. 28, flavor, microcrystalline cellulose, potassium hydroxide, potassium sorbate, purified water, salicylic acid, simethicone emulsion, sodium benzoate, sucralose, xanthan gum</p> <p>Questions? Call 800-824-1706 Monday - Friday 9am - 4pm MST</p> <p>LOT: UNVARNISHED AREA EXP:</p> <p>DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704</p> <p>WFZ001 70708WINLR</p>  <p>0 70552 24151 0</p>	<p>*Compare to the active ingredient in PEPTO-BISMOL® Ultra Strength</p>  <p>ULTRA STRENGTH Stomach Relief</p> <p>BISMUTH SUBSALICYLATE/ UPSET STOMACH RELIEVER & ANTI-DIARRHEAL</p> <p>Soothing Relief for: Upset Stomach, Indigestion, Nausea, Heartburn & Diarrhea</p>  <p>8 FL OZ (236 mL)</p>	<p>Do not use if imprinted shrink band is missing or broken</p> <p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredient (in each 15 mL dose)</th><th>Purpose</th></tr></thead><tbody><tr><td>Bismuth subsalicylate 525 mg.....</td><td>Upset stomach reliever and anti-diarrheal</td></tr></tbody></table> <p>Uses relieves ■ travelers' diarrhea ■ diarrhea ■ upset stomach due to overindulgence in food and drink, including: ■ heartburn ■ indigestion ■ nausea ■ gas ■ belching ■ fullness</p> <p>Warnings</p> <p>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.</p> <p>Allergy alert: Contains salicylate. Do not take if you are ■ allergic to salicylates (including aspirin) ■ taking other salicylate products</p> <p>Do not use if you have ■ an ulcer ■ a bleeding problem ■ bloody or black stool</p> <p>Ask a doctor before use if you have ■ fever ■ mucus in the stool</p> <p>Ask a doctor or pharmacist before use if you are taking any drug for ■ anticoagulation (thinning the blood) ■ diabetes ■ gout ■ arthritis</p> <p>When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur.</p> <p>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</p> <p><small>*This product is not manufactured or distributed by PROCTER & GAMBLE INC., distributor of PEPTO-BISMOL® Ultra Strength.</small></p>	Active ingredient (in each 15 mL dose)	Purpose	Bismuth subsalicylate 525 mg.....	Upset stomach reliever and anti-diarrheal
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WINCO FOODS ULTRA STRENGTH STOMACH RELIEF

bismuth subsalicylate suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-363
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION - UNII:ZS9CD1I8YE, SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	525 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POTASSIUM SORBATE (UNII: 1VPU26JZ4)	
WATER (UNII: 059QF0K00R)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
DIMETHICONE, UNSPECIFIED (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-363-24	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	02/25/2020	

Labeler - WINCO FOODS (056098817)