

**THREDA- bismuth subsalicylate liquid**  
**Menper Distributors, 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.*

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**Active Ingredient** (in each 15 mL tablespoon)  
Bismuth Subsalicylate 262 mg

**Purpose**

upset stomach reliever and antidiarrheal

**Uses**

Relieves:

- Heartburn
- Indigestion
- Upset Stomach
- Nausea
- 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 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
- 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 the reach of children.**

**Directions:**

Shake well before use

Adult and children 12 years and over: 1 dose (2tbsp or 30 mL) every 1/2 hour as needed, do not exceed 8 doses (16 Tbsp or 240 mL) in 24 hours.

Use until diarrhea stops, but not more than 2 days.

Children under 12 years: ask a doctor

Drink plenty of water or clear fluids to help prevent dehydration caused by diarrhea.

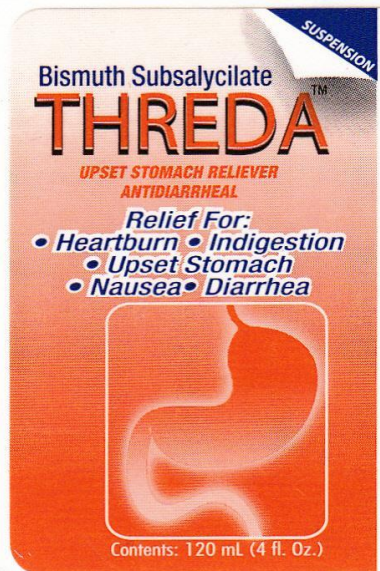
**Other Information**

Each tablespoon contains: Sodium 6 mg, Low sodium, Sugar free, Salicylate 130 mg. Protect from freezing. Avoid excessive heat (more than 140°F or 40°C)

**Tamper-Evident:** Do not use if imprinted shrinkband is missing or broken

**Inactive ingredients**

BENZOIC ACID, MAGNESIUM ALUMINUM SILICATE, METHYLCELLULOSE (100 CPS), D&C RED NO. 22, D&C RED NO. 28, SALICYLIC ACID, SODIUM SALICYLATE, SORBIC ACID, SUCRALOSE, WATER



<b>Drug Facts</b>	
<b>Active ingredient (in each 15 mL tablespoon)</b>	<b>Purpose</b>
Bismuth Subsalicylate 262 mg	upset stomach reliever and antidiarrheal
<b>Uses</b> Relieves: <input type="checkbox"/> Heartburn <input type="checkbox"/> Indigestion <input type="checkbox"/> Upset stomach <input type="checkbox"/> Nausea <input type="checkbox"/> Diarrhea	
<b>Warnings</b>	
<b>Reye's syndrome:</b> 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.	
<b>Allergy alert: Contains salicylate. Do not take if you are:</b>	
<input type="checkbox"/> Allergic to salicylates (including aspirin) <input type="checkbox"/> Taking other salicylate products	
<b>Do not use if you have:</b>	
<input type="checkbox"/> An ulcer <input type="checkbox"/> A bleeding problem <input type="checkbox"/> Bloody or black stool	
<b>Ask a doctor before use if you have:</b>	
<input type="checkbox"/> Fever <input type="checkbox"/> Mucus in the stool	
<b>Ask a doctor or pharmacist before use if you are taking any drug for:</b>	
<input type="checkbox"/> Anticoagulation (thinning the blood) <input type="checkbox"/> Diabetes <input type="checkbox"/> Gout <input type="checkbox"/> Arthritis	
<b>When using this product,</b> a temporary, but harmless, darkening of the stool and/or tongue may occur.	
<b>Stop use and ask a doctor if:</b>	
<input type="checkbox"/> Symptoms get worse <input type="checkbox"/> Ringing in the ears or loss of hearing occurs <input type="checkbox"/> Diarrhea lasts more than 2 days	
<b>If pregnant or breast-feeding,</b> ask a health professional before use	
<b>Keep out of the reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. ▶	

<b>Drug Facts (continued)</b>
<b>Directions:</b>
<b>Shake well before use</b>
<b>Adult and children 12 years and over:</b> 1 dose (2 tbsp or 30 mL) every 1/2 hour as needed, do not exceed 8 doses (16 Tbsp or 240 mL) in 24 hours.
Use until diarrhea stops, but not more than 2 days
<b>Children under 12 years: ask a doctor</b>
Drink plenty water or clear fluids to help prevent dehydration caused by diarrhea.
<b>Other information</b>
Each tablespoonful contains: Sodium 6 mg, Low sodium, Sugar free, Salicylate 130 mg. Protect from freezing. Avoid excessive heat (more than 140°F or 40°C)
<b>Tamper-Evident:</b> Do not use if imprinted shrinkband is missing or broken
<b>Inactive ingredients:</b> benzoic acid, flavor, magnesium aluminum silicate, methylcellulose, red 22, red 28, salicylic acid, sodium salicylate, sorbic acid, sucralose, and water
<b>Modo de uso</b>
<b>Agítese antes de usarse</b>
<b>Adultos y niños mayores de 12 años:</b>
Una dosis (2 cucharadas o 30 mL) cada 1/2 hora según necesidad, no exceder de 8 dosis (16 cucharadas 240 mL) en 24 horas. Use mientras tenga diarrea, pero por no más de 2 días.
<b>Niños menores de 12 años,</b> consultar al doctor.
Tomar bastante agua o fluidos claros para prevenir deshidratación causada por la diarrea.

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**THREDA**

bismuth subsalicylate liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53145-057
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg in 15 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>METHYLCELLULOSE (100 CPS)</b> (UNII: 4GFU244C4J)	
<b>D&amp;C RED NO. 22</b> (UNII: 1678RKX8RT)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>SODIUM SALICYLATE</b> (UNII: WIQ1H85SYP)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:53145-057-04	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		

**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	02/21/2012	

**Labeler** - Menper Distributors, Inc. (101947166)

Revised: 9/2013

Menper Distributors, Inc.