

# **BISMUTH SUBSALICYLATE- bismuth subsalicylate capsule, liquid filled Softgel Healthcare Pvt Ltd**

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**Bismuth Subsalsicylate Capsules 262 mg**

## **Active ingredient (in each softgel)**

Bismuth subsalicylate 262 mg

## **Purpose**

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 and vomiting occur, consult a doctor because these symptoms could be an early sign 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.

**Directions**

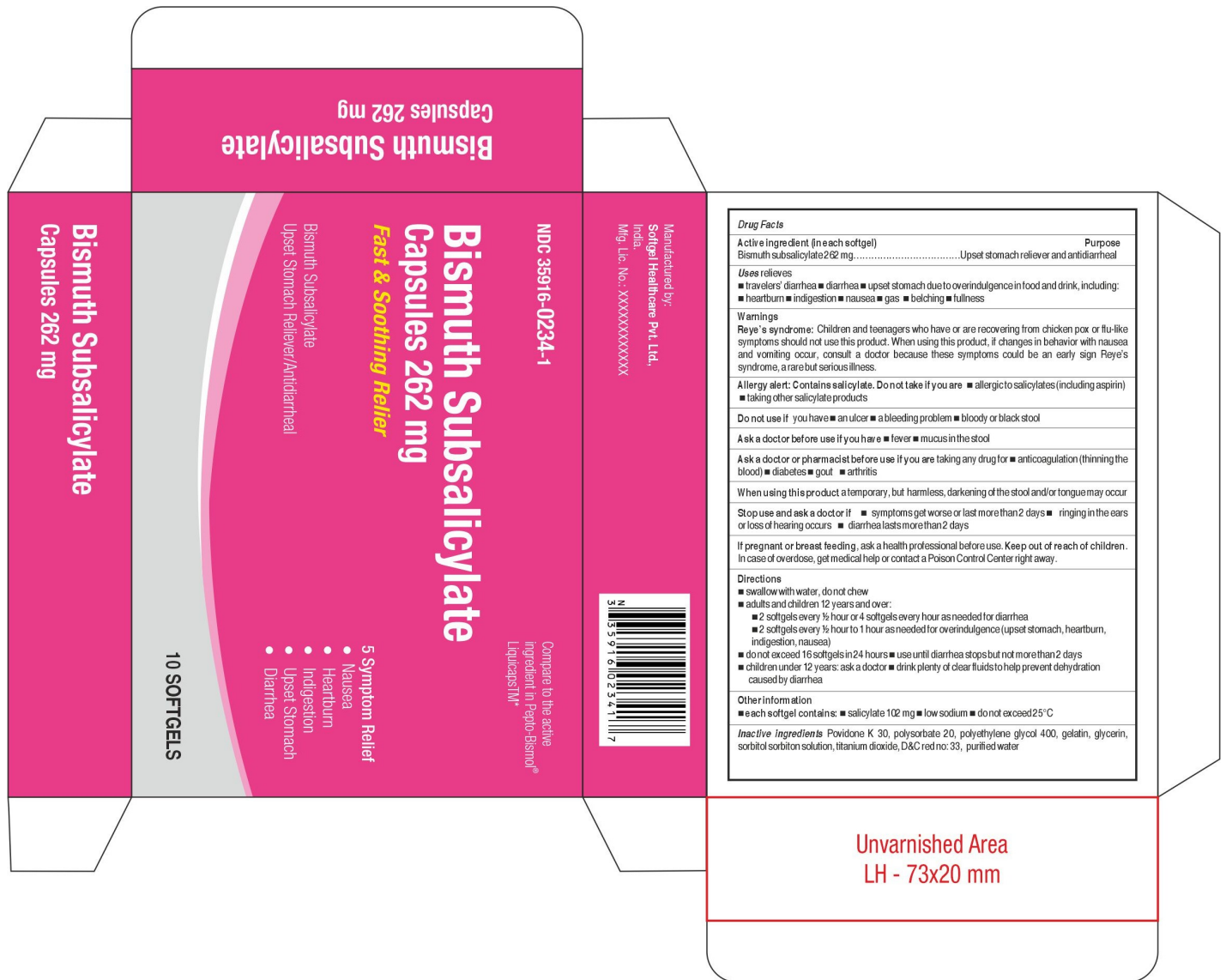
- swallow with water, do not chew
- adults and children 12 years and over:
  - 2 softgels every ½ hour or 4 softgels every hour as needed for diarrhea
  - 2 softgels every ½ hour to 1 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 16 softgels in 24 hours
- 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 softgel contains:**

- salicylate 102 mg
- low sodium
- do not exceed 25°C

## Inactive ingredients



Unvarnished Area  
LH - 73x20 mm

## BISMUTH SUBSALICYLATE

bismuth subsalicylate capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0234
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>	pink (Opaque)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (oblong)	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0234-1	1 in 1 CARTON	05/27/2024	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M008	05/27/2024	

**Labeler** - Softgel Healthcare Pvt Ltd (675584180)

Revised: 5/2024

Softgel Healthcare Pvt Ltd