REGULAR STRENGTH STOMACH RELIEF- bismuth subsalicylate tablet, chewable
DOLGENCORP, 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.

727R Dollar General 55910-204 Bismuth Subsalicylate tablets 262 mg

Drug Facts

Active ingredient (in each tablet)
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:
o heartburn
o indigestion
o nausea
o gas
o belching
o 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 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 (1-800-222-1222).

Directions

chew or dissolve in mouth
adults and children 12 years and over:
- 2 tablets (1 dose) every ½ hour or 4 tablets (2 doses) every hour as needed for diarrhea
- 2 tablets (1 dose) every ½ hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)

do not exceed 8 doses (16 tablets) 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 tablet contains:** calcium 140 mg
- salicylate 101 mg
- low sodium
- avoid excessive heat (over 104°F or 40°C)

Inactive ingredients calcium carbonate, D&C red #27 lake, flavor, magnesium stearate, mannitol, povidone, saccharin sodium, talc

Questions or comments?

call **1-877-290-4008**

REGULAR STRENGTH STOMACH RELIEF

bismuth subsalicylate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-204
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

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	

TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	

Product Characteristics

Color	pink (Light pink to pink)	**Score**	no score
Shape	ROUND	**Size**	15mm
Flavor		**Imprint Code**	118
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-204-30	5 in 1 CARTON	09/18/2023	
1		6 in 1 CELLO PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M008	09/18/2023	

Labeler - DOLGENCORP, INC. (068331990)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
Marksans Pharma Ltd		925822975	manufacture(55910-204)

Revised: 9/2023 DOLGENCORP, INC.