

DEVROM- bismuth subgallate capsule

The Parthenon Co., 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.

Devrom®

Drug Facts

Active ingredient (in each capsule)

Bismuth subgallate 200 mg

Purpose

Internal Deodorant

Use for eliminating or reducing odor from flatulence (gas) and stool (feces).

Warnings

- **If pregnant or breast-feeding**, ask a health professional before use.
- When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur.
- In case of overdose, get medical help or contact a Poison Control Center right away.

- **Keep out of reach of children.**

Directions

- Adults and children 12 years and over: 1 to 2 capsules up to four times daily or as directed by physician.
- Do not exceed 8 capsules in 24 hours.
- Children under 12 years: ask a doctor.

Other Information

- This product cannot be expected to be effective in the reduction of odor due to faulty personal hygiene.
- Does not contain gluten, lactose, or salicylates.
- Store in a cool, dry place. Do not use if outer safety seal or printed inner safety seal is broken.

Inactive ingredients

microcrystalline cellulose, maltodextrine, croscarmellose, silica, magnesium stearate.

Questions?

1-800-453-8898

**Manufactured for and distributed by
The Parthenon Company, Inc.**

PRINCIPAL DISPLAY PANEL - 200 mg Capsule Bottle Label

Devrom®
(200 mg bismuth subgallate)

Internal Deodorant
100 capsules

8
66344100031
7
PW1999 NDC 49309-002-01
Made in U.S.A.



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www.devrom.com



DEVROM

bismuth subgallate capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49309-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBGALLATE (UNII: YIW503M7V) (BISMUTH CATION - UNII: ZS9CD118YE)	BISMUTH SUBGALLATE	200 mg

Inactive Ingredients

Ingredient Name	Strength
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose (UNII: OP1R32D61U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
croscarmellose sodium (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	YELLOW (CLEAR)	Score	no score
Shape	CAPSULE	Size	19 mm

Flavor		Imprint Code	Devrom	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49309-002-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part357I	12/01/2018		

Labeler - The Parthenon Co., Inc. (073014607)

Revised: 12/2018

The Parthenon Co., Inc.