

STIMULANT LAXATIVE ENTERIC COATED- bisacodyl tablet
SDA Laboratories, Inc.

Active ingredient (in each tablet)

Bisacodyl 5 mg

Purpose

Stimulant Laxative

Uses

- for relief of occasional constipation and irregularity
- this product generally produces bowel movement in 6 to 12 hours

Warnings

Do not use if you cannot swallow without chewing

Ask a doctor before use if you have

- stomach pain, nausea, vomiting
- noticed a sudden change in bowel habits that lasts more than 2 weeks

When using this product

- do not chew or crush tablet(s)
- do not use within 1 hour after taking an antacid or milk
- it may cause stomach discomfort, faintness and cramps

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

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

- take with a glass of water
- **do not take more than directed**
- adults and children 12 years and older: take 1 to 3 tablets in a single daily dose
- children 12 and under: ask a doctor

Other information

- store at controlled room temperature 20°-25°C (68°-77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive humidity
- package not child resistant

Inactive ingredients

acacia, ammonium hydroxide, calcium carbonate, corn starch, D&C yellow #10 lake, FD&C yellow #6 lake, hypromellose, iron oxide black, lactose, magnesium stearate, methylparaben, PEG, polydextrose, polyvinyl acetate phthalate, propylparaben, propylene glycol, povidone, shellac, simethicone, silica, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate, wax.

Questions or comments?

1-203-861-0005

Manufactured for:

SDA Laboratories, Inc.

New York, NY

PRINCIPAL DISPLAY PANEL

*Compare to active ingredient in Dulcolax® Laxative

NDC 66424-002-01

STIMULANT LAXATIVE

• For Gentle Relief of Constipation

BISACODYL 5 mg
ENTERIC COATED TABLETS

100 Tablets

Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

Drug Facts

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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ▶

*This product is not manufactured or distributed by the owner registered trademark DULCOLAX®. Manufactured for: SDA Laboratories, Inc. New York, NY • Questions? 1-203-861-0005

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R441-0525

PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)

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STOP PEELING

STIMULANT LAXATIVE ENTERIC COATED			
bisacodyl tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66424-002
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)		BISACODYL	5 mg
Inactive Ingredients			
Ingredient Name			Strength
SODIUM ALGINATE (UNII: C269C4G2ZQ)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			

STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ACACIA (UNII: 5C5403N26O)	
AMMONIA (UNII: 5138Q19F1X)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66424-002-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	07/01/2025	

Labeler - SDA Laboratories, Inc. (948067889)

Registrant - SDA Laboratories, Inc. (948067889)

Establishment

Name	Address	ID/FEI	Business Operations
Geri-Care Pharmaceutical Corp		611196254	manufacture(66424-002)

Revised: 5/2025

SDA Laboratories, Inc.