

**BISACODYL ENTERIC- bisacodyl enteric tablet, coated  
DIRECT RX**

*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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**BISACODYL**

Bisacodyl 5mg

Do not use

Do not use if you cannot swallow without chewing

Ask a doctor before use if

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

When using this product

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

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

Pregnancy/Breastfeeding

ask a health professions before use.

Keep out of reach of children

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

Stimulant laxative

- relieves occasional constipation and irregularity
- this product generally produces bowel movement in 6 to 12 hours
- take with a glass of water

adults and children 12 years and over- take 1 to 3 tablets in a single daily dose

children 6 to under 12 years of age - take 1 tablet in a single daily dose

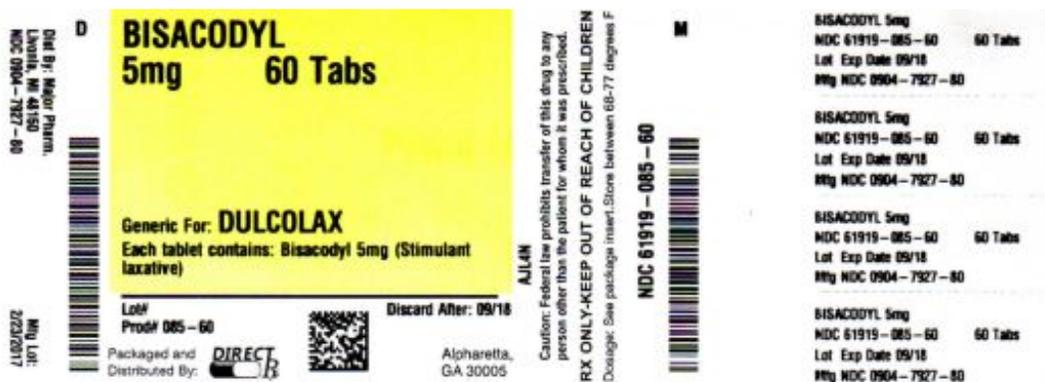
children under 6 years of age - ask a doctor

-store at 25 degrees C (77 degrees F) excursions permitted between 15 degrees-30 degrees C (59 degrees-86 degrees F)

- use by expiration date on package
- protect from excessive humidity

acacia, bees wax, calcium sulfate, carnauba wax, cellulose, corn starch, D&C Yellow No. 10 lake,

FD&C Yellow No. 6 lake, gelatin, lactose, magnesium stearate, pharmaceutical glaze, polyvinyl acetate phthalate, silica gel, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide.



## BISACODYL ENTERIC

bisacodyl enteric tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61919-085(NDC:0904-7927)
<b>Route of Administration</b>	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
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
AMMONIUM NONOXYNOL-4 SULFATE (UNII: 9HIA70O4J0)	
SHELLAC (UNII: 46N107B71O)	
ACACIA (UNII: 5C5403N26O)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	5
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-085-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2017	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/24/2017	

**Labeler** - DIRECT RX (079254320)**Registrant** - DIRECT RX (079254320)**Establishment**

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-085)