

**BISACODYL- bisacodyl tablet**  
**Chain Drug Consortium**

*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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**Premier Value 44-327**

***Active ingredient (in each tablet)***

Bisacodyl USP, 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**

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

**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 (1-800-222-1222) right away.

***Directions***

- take with a glass of water

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adults and children | take 1 to 3 tablets

12 years and over	in a single daily dose
children 6 to under 12 years	take 1 tablet in a single daily dose
children under 6 years	ask a doctor

### ***Other information***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive humidity
- see end flap for expiration date and lot number

### ***Inactive ingredients***

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

### ***Questions or comments?***

**1-800-426-9391**

### **Principal Display Panel**

**Premier  
Value<sup>®</sup>**

**\*COMPARE TO THE ACTIVE INGREDIENT IN  
DULCOLAX<sup>®</sup> LAXATIVE TABLETS**

**Bisacodyl, 5 mg  
Bisacody USP, 5 mg**

**STIMULANT LAXATIVE**

Gentle, dependable  
constipation relief

Comfort coated

**100 Tablets**

**actual size**

**INDEPENDENTLY TESTED**

**PV**

**SATISFACTION GUARANTEED**

\*This product is not manufactured or distributed by Sanofi-Aventis Deutschland GMBH, owner of the registered trademark Dulcolax<sup>®</sup> Laxative Tablets.

50844 REV0119A32712

Distributed By:  
Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,  
Wayne, PA 19087

**If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING**



COMPARE TO THE ACTIVE INGREDIENT IN  
DULCOLAX® LAXATIVE TABLETS

# Bisacodyl, 5 mg

Bisacodyl USP, 5 mg  
**STIMULANT LAXATIVE**

Gentle, dependable  
constipation relief



100 Tablets Comfort coated



**Bisacodyl, 5 mg**  
Bisacodyl USP, 5 mg  
**STIMULANT LAXATIVE**

100 Tablets



B-1590-327-12  
REV0119A32712



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**Drug Facts (continued)**

■ 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 (1-800-222-1222) right away.

**Directions** ■ take with a glass of water

adults and children take 1 to 3 tablets

12 years and over in a single daily dose

children 6 to under take 1 tablet in a single daily dose

children under 6 ask a doctor

**Other information**

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

■ avoid excessive humidity

■ see end flap for expiration date and lot number

**Inactive ingredients** acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black.

**Drug Facts (continued)**

lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac glaze, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, tracefin, triethyl citrate

**Questions or comments?**  
1-800-426-9391

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**Drug Facts (continued)**

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- 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
- you may have stomach discomfort, faintness and 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.

**Drug Facts**  
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

**Active ingredient**  
Bisacodyl USP, 5 mg, . . . . . Stimulant laxative

**Purpose**  
■ stomach pain, nausea or vomiting

**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.

# BISACODYL

bisacodyl tablet

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-688
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

## Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
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)	
AMMONIA (UNII: 5138Q19F1X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

## Product Characteristics

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

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-688-25	1 in 1 CARTON	03/25/2002	
1		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:68016-688-10	1 in 1 CARTON	03/25/2002	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	03/25/2002	

**Labeler** - Chain Drug Consortium (101668460)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(68016-688)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(68016-688)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(68016-688)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(68016-688)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(68016-688)