

GENTLE LAXATIVE- bisacodyl tablet, coated
Topco Associates, LLC

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.

Topcare 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

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

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 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.
- 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 12 years and over	take 1 to 3 tablets in a single daily dose
children 6 to 12 years	take 1 tablet in a single daily dose
children under 6 years	ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- avoid excessive humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- 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?

1-888-423-0139

Principal display panel

+TopCare

Health™

hDC 36800-327-03

COMPARE TO
DULCOLAX® LAXATIVE
TABLETS ACTIVE
INGREDIENT*

**Gentle
Laxative**

BISACODYL USP 5 mg • STIMULANT LAXATIVE

**Gentle, Dependable Overnight
Relief from Constipation**

10 COMFORT COATED TABLETS

actual
size

• our pharmacist recommended •

**TAMPER EVIDENT: DO NOT USE IF
PACKAGE IS OPENED OR IF BLISTER
UNIT IS TORN, BROKEN OR SHOWS
ANY SIGNS OF TAMPERING**

*This product is not manufactured or distributed by
Sanofi-Aventis Deutschland GMBH, owner of the registered
trademark Dulcolax® Laxative Tablets.
50844 ORG011932703

ELK GROVE VILLAGE, IL 60007

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QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

Visit here for more information:

<http://topbrnds.com/48ztk3>

QUALITY GUARANTEED



SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STARCH, CORN (UNII: O8232NY3SJ)
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)
MAGNESIUM STEARATE (UNII: 70097M6I30)
METHYLPARABEN (UNII: A2I8C7HI9T)
POLYDEXTROSE (UNII: VH2XOU12IE)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
SHELLAC (UNII: 46N107B71O)
DIMETHICONE (UNII: 92RU3N3Y1O)
WATER (UNII: 059QF0K00R)
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)

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:36800-327-03	1 in 1 CARTON	05/15/2019	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	05/15/2019	

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(36800-327)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(36800-327)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(36800-327)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(36800-327)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(36800-327)