

GENTLE LAXATIVE- bisacodyl tablet, delayed release
Topco Associates, LLC

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)
- it may cause 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 right away.

Directions

- **do not take more than directed**
- 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	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

NDC 36800-327-03

COMPARE TO
DULCOLAX® LAXATIVE
TABLETS ACTIVE
INGREDIENT*

**Gentle
Laxative**

BISACODYL USP 5 mg • STIMULANT LAXATIVE

**Gentle, Dependable
Constipation Relief**

25 COMFORT COATED

actual
size

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 A. Nattermann & Cie. GmbH, owner of the registered trademark Dulcolax® Laxative Tablets.
50844 REV0923B32703

QUALITY GUARANTEED

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ITASCA, IL 60143

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QUESTIONS? 1-888-423-0139

topcare@topco.com

www.topcarebrand.com

TopCare[®] health

Gentle Laxative

BISACODYL USP 5 mg • STIMULANT LAXATIVE

10 COMFORT COATED TABLETS

actual size

NDC 36800-327-03

COMPARE TO DULCOLAX[®] LAXATIVE TABLETS ACTIVE INGREDIENT*

Drug Facts

Active ingredient (in each tablet) Bisacodyl USP, 5 mg Stimulant laxative

Purpose

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- this product generally produces bowel movement in 6 to 12 hours

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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

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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcareand.com
QUALITY GUARANTEED

Scan here for more information or call 1-888-423-0139

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

No print/No varnish Lot & Exp date

Barcode: 36800 46115 4

B-1910-327-03-BR
REV0923832703

LEBG3015G

TopCare 44-327

GENTLE LAXATIVE

bisacodyl tablet, delayed release

Product Information

Product Type

HUMAN OTC DRUG

Route of Administration

ORAL

Item Code (Source)

NDC:36800-327

Active Ingredient/Active Moiety

Ingredient Name

BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)

Basis of Strength

BISACODYL

Strength

5 mg

Inactive Ingredients

Ingredient Name

ACACIA (UNII: 5C5403N26O)

AMMONIA (UNII: 5138Q19F1X)

CALCIUM CARBONATE (UNII: H0G9379FGK)

CARNAUBA WAX (UNII: R12CBM0EIZ)

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)

FERROSOFERRIC 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: 059QF0KO0R)

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			
2	NDC:36800-327-56	1 in 1 CARTON		05/15/2019	
2		25 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 Drug		505G(a)(3)		05/15/2019	

Labeler - Topco Associates, LLC (006935977)

Establishment

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

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(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.		117025878	manufacture(36800-327)

