

BISACODYL ENTERIC COATED- bisacodyl tablet, coated
TOP CARE (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.

Drug Facts

Active ingredient (in each tablet)

Bisacodyl USP 5 mg

Purpose

Stimulant laxative

Use

- for temporary relief of occasional constipation and irregularity
- this product generally produces a 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 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 pregnancy or breast-feeding,

ask a health professions 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

adults and children 12 yrs of age 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

Other information

- store between 20°-25°C (68°-77°F)

Inactive ingredients

acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, iron oxide, iron oxide black, iron oxide yellow (iron oxide ochre), magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, and titanium dioxide

Questions or comments?

Cal toll free **1-888-423-0139**

Principal Display Panel

COMPARE TO DULCOLAX® LAXATIVE TABLETS ACTIVE INGREDIENT*

Gentle Laxative

BISACODYL 5 mg • STIMULANT LAXATIVE

Gentle, Predictable Overnight Relief from Constipation

COMFORT COATED TABLETS

*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor of Dulcolax® Laxative Tablets.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60077

QUESTIONS? 1-888-423-0139

topcare@topco.com

Product Label

NDC 36800-190-03



COMPARE TO
DULCOLAX® LAXATIVE
TABLETS ACTIVE
INGREDIENT*

Gentle Laxative



BISACODYL 5 mg • STIMULANT LAXATIVE

Gentle, Predictable Overnight
Relief from Constipation

25 COMFORT COATED
TABLETS



actual
size

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:
Exp. Date:

*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor of Dulcolax® Laxative Tablets.

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007
© TOPCO PLVA0618 QUESTIONS? 1-888-423-0139 topcare@topco.com
www.topcarebrand.com

Visit here for more information: <http://topbrnds.com/48zr8t>

✓ QUALITY GUARANTEED

GLUTEN
FREE

PLD-D23K FC004519



<p>Other information</p> <p>■ store between 20-25°C (68-77°F)</p> <p>Inactive ingredients acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, iron oxide, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide</p> <p>Questions or comments? Call toll free 1-888-423-0139</p>	<p>■ do not change if better than 2 weeks</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ 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 <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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
--	--

<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>		<p>Drug Facts</p> <p>Active ingredient (in each tablet) Bisacodyl USP 5 mg..... Stimulant laxative</p>	
<p>Directions</p> <p>take with a glass of water</p> <p>adults and children take 1 to 3 tablets in 12 years of age and over</p> <p>children 6 to under 12 take 1 tablet in a single daily dose</p> <p>children under 6 years of age ask a doctor</p>		<p>Use</p> <p>for temporary relief of occasional constipation and irregularly</p> <p>this product generally produces a bowel movement in 6 to 12 hours</p>	
<p>Warnings</p> <p>Do not use if you cannot swallow without chewing.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> stomach pain, nausea or vomiting a sudden change in bowel habits that lasts more 		<p>Purpose</p> <p>Stimulant laxative</p>	

TOPCARE HEALTH Gentle Laxative

BISACODYL ENTERIC COATED

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-190
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
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)
SUCROSE (UNII: C151H8M554)
POVIDONE (UNII: FZ989GH94E)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	TCL003
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-190-25	1 in 1 CARTON	01/10/2013	
1		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 not final	part334	01/10/2013	

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 12/2022

TOP CARE (Topco Associates LLC)