

**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.*

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**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

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take 1 to 2 tablets in a single daily

adults and children 12 years 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?

Call 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

**TopCare**<sup>®</sup>  
health™

COMPARE TO  
DULCOLAX<sup>®</sup> 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<sup>®</sup> Laxative Tablets.

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007  
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www.topcarebrand.com

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✓ **QUALITY GUARANTEED**

GLUTEN  
FREE

PLD-D23K FC004519



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**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, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl acetate phtalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

**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

<p><b>Drug Facts (continued)</b></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><b>Drug Facts</b></p> <p><b>Active ingredient</b> (in each tablet) Bisacodyl USP 5 mg..... Stimulant laxative</p>	
<p><b>Directions</b></p> <p>take with a glass of water</p> <p>adults and children 12 years of age and over take 1 to 3 tablets in a single daily dose</p> <p>children 6 to under 12 years of age take 1 tablet in a single daily dose</p> <p>children under 6 years of age ask a doctor</p>		<p><b>Use</b></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><b>Warnings</b></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"> <li>stomach pain, nausea or vomiting</li> <li>a sudden change in bowel habits that lasts more</li> </ul>		<p><b>Purpose</b></p>	

TOPCARE HEALTH Gentle Laxative

**BISACODYL ENTERIC COATED**

bisacodyl tablet, coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-190
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y61) (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)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

Product Characteristics			
Color	ORANGE	Score	no score
Shape	ROUND	Size	6 mm
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)