

**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 (PEG) 400, 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

OVERNIGHT RELIEF

#### Laxative Tablets

Bisacodyl, USP 5 mg

- **Gentle, predictable, overnight relief from constipation**

*COMPARE TO DULCOLAX® active ingredient\**

Enteric Coated Tablets

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

**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®

OVERNIGHT RELIEF

# Laxative Tablets

BISACODYL, USP 5 MG

- Gentle, predictable, overnight relief from constipation

actual size



COMPARE TO DULCOLAX® active ingredient\*

25 ENTERIC COATED 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.

Lot No.:  
Exp. Date:

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

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This TOPCARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

PLD-C23J FC002023



### Questions or comments?

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**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 (PEG) 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

### Other information

store between 20°-25°C (68°-77°F)

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

### Directions

take with a glass of water

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

### Purpose

Stimulant laxative

### Active ingredient (in each tablet)

Bisacodyl USP 5 mg

If pregnant or breast-feeding, ask a health professional before use.  
If you need to use a laxative for more than 1 week

you could be signs of a serious condition. movement after using this product. These

Stop use and ask a doctor if you have rectal bleeding or no bowel

it may cause stomach discomfort, flatness and cramps

When using this product do not use within 1 hour after taking an

more than 2 weeks

Ask a doctor before use if you have stomach pain, nausea or vomiting

Do not use if you cannot swallow without chewing.

### Warnings

for temporary relief of occasional constipation and irregularly

Use this product generally produces a bowel movement in 6 to 12 hours

Do not use if you cannot swallow without chewing.

## Top Care Laxative Tablet

**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: 10 X0709Y6I) (BISACODYL - UNII:10 X0709Y6I)	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)	
POVIDONES (UNII: FZ989GH94E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

**Product Characteristics**

<b>Color</b>	ORANGE	<b>Score</b>	no score
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<b>Shape</b>	ROUND	<b>Size</b>	6 mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL003
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-190-25	1 in 1 CARTON		
1		25 in 1 BLISTER PACK		

### 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: 6/2014

TOP CARE (Topco Associates LLC)