

**LAXATIVE ENTERIC COATED- bisacodyl tablet, coated**  
**P & L Development, 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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**Bisacodyl Enteric Coated Tablet**

**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 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 for more than 2 weeks

**When using this product**

- do not chew or crush tablet(s)
- it may cause stomach discomfort, faintness and cramps
- do not use within 1 hour after taking an antacid or milk

**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 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**

- take with a glass of water

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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 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

\*Compare to the active ingredient in DULCOLAX®\*

#### **LAXATIVE**

Bisacodyl, 5 mg stimulant laxative

Gentle, Predictable, Overnight relief

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

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**Distributed by:**

**PL Developments**

**200 Hicks St Westbury, NY 11590 USA**

**Package Label**

Compare to the active ingredient in Dulcolax® Laxative\*

**ready incase**  
NDC 59726-190-08

**laxative**  
**bisacodyl 5 mg**  
**stimulant laxative**

gentle predictable overnight relief

**25 enteric coated tablets**

PLD-423K  
L8009342  
Distributed by:  
PI Developments  
200 Hicks Street  
Westbury, NY 11590

Lot No: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

**TAKE CARE: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

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**Questions or comments?** Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

**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 phthalate, povidone, stearic acid, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

**Directions** ■ Take with a glass of water  
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children 6 to under 12 take 1 tablet in a single daily dose  
children under 6 years ask a doctor

**Drug Facts**

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**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 ■ if you may cause stomach discomfort, flatness 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

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### Readyincase Laxative Bisacodyl

## LAXATIVE ENTERIC COATED

bisacodyl tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59726-190
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

### Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDRO US (UNII: E934B3V59H)	
ANHYDRO US LACTOSE (UNII: 3S Y5LH9 PMK)	
CARNAUBA WAX (UNII: R12CBM0 EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
GELATIN (UNII: 2G86QN327L)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	TCL;003
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-190-03	1 in 1 CARTON	09/01/2010	
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	09/01/2010	

**Labeler** - P & L Development, LLC (800014821)