LAXATIVE ENTERIC COATED- bis acodyl 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.

Bis acodyl 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

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

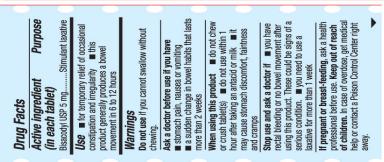
Distributed by:

PL Developments

200 Hicks St Westbury, NY 11590 USA

Package Label





Readyincase Laxative Bisacodyl

LAXATIVE ENTERIC COATED

bisacodyl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-190
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 ANHYDRO US (UNII: E934B3V59H)		
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
STARCH, CORN (UNII: O8232NY3SJ)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
ALUMINUM O XIDE (UNII: LMI26O6933)		
GELATIN (UNII: 2G86QN327L)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		

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

F	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)

Revised: 12/2019 P & L Development, LLC