

LAXATIVE TABLETS- bisacodyl tablet, delayed release

Marc Glassman, Inc.

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.

Laxative

Active ingredient

Bisacodyl USP 5mg

Purpose

Stimulant Laxative

Uses

- for relief of occasional constipation and irregularity
- this product usually causes bowel movements in 6 to 12 hours

Warnings

Do not use

if you cannot swallow without chewing.

Ask a doctor before use if you have

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits that persists over a period of 2 weeks

When using this product

- do not chew or crush
- do not take this product within 1 hour of taking antacid or milk
- you may have stomach discomfort, faintness or cramps

Stop use and ask a doctor if

- rectal bleeding or failure to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

Pregnancy/Breastfeeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. In case of accidental overdose, get medical help or contact a doctor or Poison Control Center (1-800-222-1222) right away.

Directions

- take with water
- **Adults and children 12 years of age and older:** take 1 to 3 tablets in a single dose, once daily
- **Children 6 to 12 years of age:** take 1 tablet once daily
- **Children under 6 years of age:** consult a doctor

Other information

- store between 68° to 77°F (20° to 25°C)
- do not use blister unit is broken or torn

Inactive ingredients

acacia, anhydrous calcium sulfate, carnauba wax, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, iron oxide black, iron oxide red, iron oxide yellow, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, polyvinyl acetate phthalate, povidone, shellac, silicon dioxide, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

Principal Display Panel

NDC 68998-226-92

*Compare to the active ingredient in Dulcolax®

Marc's

Laxative
Bisacodyl 5 mg

Laxative
Bisacodyl 5 mg

Marc's

Laxative
Bisacodyl 5 mg

Laxative
Bisacodyl 5 mg

Enteric Coated

Bisacodyl 5 mg

Gentle & Effective
Overnight Relief

25 Tablets

Drug Facts	
Active Ingredient (in each tablet) Bisacodyl USP 5mg	Purpose Stimulant Laxative
Uses ■ for relief of occasional constipation and irregularity ■ this product usually causes bowel movements in 6 to 12 hours	
Warnings Do not use if you cannot swallow without chewing. Ask a doctor before use if you have ■ abdominal pain, nausea or vomiting ■ a sudden change in bowel habits that persists over a period of 2 weeks When using this product ■ do not chew or crush ■ do not take this product within 1 hour of taking antacid or milk ■ you may have stomach discomfort, faintness or cramps Stop use and ask a doctor if ■ rectal bleeding or failure to have a bowel movement after use of a laxative. 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 accidental overdose, get medical help or contact a doctor or Poison Control Center (1-800-222-1222) right away.	
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*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., owner of the registered trademark Dulcolax®

Distributed by:
Marc Glassman, Inc.
West 130th Street
Cleveland, OH 44130

LB1241
R1116

0 94442 00146 6

Laxative

LAXATIVE TABLETS

bisacodyl tablet, delayed release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68998-226

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)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	TCL;003
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-226-92	1 in 1 CARTON	07/01/2014	
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	07/01/2014	

