THE MEDICINE SHOPPE GENTLE LAXATIVE- bis acodyl tablet The Medicine Shoppe International

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.

The Medicine Shoppe Gentle Laxative

Active ingredient(s)

Bisacodyl USP 5 mg

Purpose

Stimulant Laxative

Use(s)

- 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 more than 2 weeks

When using this product

- do not chew or crush tablet(s)
- it may cause stomach discomfort, faintness or 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

adults and children 12 years 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

- each tablet contains: sodium less than 0.5mg
- store at 20°-25°C (68°-77°F)
- protect from excessive humidity
- **TAMPER EVIDENT:** Blister packaged for your protection. Do not use if individual seals are broken

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.

Principal Display Panel

The Medicine Shoppe

Gentle Laxative

Overnight Relief of Constipation and Irregularity

*Compare to the active ingredient of Dulcolax®

LAXATIVE

Bisacodyl USP, 5 mg

25 Coated Tablets

CIN 1796986

Distributed By:

The Medicine Shoppe International, Inc.

Earth City MO 63045

www.medicineshoppe.com

A Cardinal Health Company

Questions? 1-800-325-1397

overnight relief of constipation and irregularity



GENTLE LAXATIVE

Medicine Shoppe &

NDC 49614-131-63

5

EXP:

GENTLE LAXATIVE

Bisacodyl USP 5 mg

Overnight relief of constipation and irregularity





*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., the owner of the registered trademark of Dulcolax®



MEDICINE SHOPPE® GUARANTEE
IF YOU ARE NOT FULLY SATISFIED WITH THIS PRODUCT,
SIMPLY RETURN THE UNUSED PORTION FOR
REPLACEMENT OR FULL REFUND OF PURCHASE PRICE.

Distributed by Medicine Shoppe International, Inc. Earth City, MO 63045 www.medicineshoppe.com A Cardinal Health Company Questions? 1-800-325-1397 CIN 1796986



GENTLE LAXATIV

aluminum lake, gelatin, iron oxide, iron oxide bláck, 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. wax, colloidal silicon dioxide, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 Inactive ingredients acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba

Blister packaged for your protection. Do not use if individual seals are broken Other information = each tablet contains: sodium less than 0.5 mg = store at 20-25 C (68-77*f) = protect from excessive humidity = TAMPER EVIDENT:

ask a doctor	children under 6 years of age
† tablet in a single daily dose	children 6 to under 12 years of age
1 to 3 tablets in a single daily dose	adults and children 12 years and over
	Directions take with a glass of water

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.

■ you need to use a laxative for more than 1 week

using this product. These could be signs of a serious condition. Stop use and ask a doctor if a you have rectal bleeding or no bowel movement after

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

Ask a doctor before use if you have = stomach pain, nausea or vomiting a s sudden change in bowel habits that lasts more than 2 weeks

Do not use if you cannot swallow without chewing Marnings

■ this product generally produces bowel movement in 6 to 12 hours **USB** • for temporary relief of occasional constipation and irregularity

THE MEDICINE SHOPPE GENTLE LAXATIVE

bisacodyl tablet

\mathbf{r}		1 .	T (. •
ν	rn	duct	Into	rma	tinn.
_	1 U	uuct	11110	1 IIIu	uvii

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49614-131

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BISACODYL (UNII: 10 X0709 Y61) (BISACODYL - UNII:10 X0709 Y61) BISACODYL 5 mg

Inactive Ingredients

inactive ingredients	
Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0 EIZ)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ACETATE PHTHALATE (UNII: 58 QVG85GW3)	
PO VIDO NE (UNII: FZ989 GH94E)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

STEARIC ACID (UNII: 4ELV7Z65AP)
SUCROSE (UNII: C151H8 M554)
TALC (UNII: 7SEV7J4R1U)

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49614-131-63	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	10/14/2011	

Labeler - The Medicine Shoppe International (071997654)

Revised: 2/2012 The Medicine Shoppe International