

GENTLE LAXATIVE - bisacodyl tablet, coated
Kareway Product, 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.

Drug facts

Active ingredient (in each tablet)

Bisacodyl USP 5 mg

Purpose

Stimulant laxative

Uses

- 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)
- 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 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 of age and over	1 to 3 tablets in a single daily dose
	1 tablet in a single daily

children 6 to under 12 years of age	1 tablet in a single daily dose
children under 6 years of age	ask a doctor

Other information

- store at 20° - 25°C (68° - 77°F)
- protect from excessive humidity
- blister packaged for your protection. Do not use if individual seals are broken.

Inactive ingredients

acacia, carnauba wax, corn starch, gelatin, glycerin esters of fatty acids, hypromellose phthalate 200731, lactose hydrate, magnesium stearate, polyethylene glycol 400, povidone, precipitated calcium carbonate, sucrose, talc, titanium oxide, yellow no. 4

Package label

Gentle Laxative

OVERNIGHT RELIEF

Gentle Laxante
Laxative
Bisacodyl USP 5 mg each

Pure-Aid™ NDC No. 67510-0171-2

**Compare to the active ingredient in Dulcolax®*

Gentle Laxante
Laxative
Bisacodyl USP 5 mg each

MAXIMUM STRENGTH

BIS BIS

TABLETS 20
COMFORT COATED

8 56023 00171 1

Exclusively distributed by:
Kareway Product Inc.
Compton, CA 90220
Made in Korea

Drug Facts (continued)
Inactive ingredients acacia, carnauba wax, corn starch, gelatin, glycerin esters, fatty acids, hypromellose phthalate 200731, lactose hydrate, magnesium stearate, polyethylene glycol 400, povidone, precipitated calcium carbonate.

Drug Facts

Active ingredient (in each tablet)
 Bisacodyl USP 5 mg.....Stimulant laxative

Purpose

■ 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
 ■ 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 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 of age and over 1 to 3 tablets in a single daily dose
 children 6 to under 12 years of age 1 tablet in a single daily dose
 children under 6 years of age ask a doctor

Other information ■ store at 20° - 25°C (68° - 77°F) ■ protect from excessive humidity
 ■ blister packaged for your protection. Do not use if individual seals are broken

Drug Facts (continued)
 sucrose, talc, titanium oxide, yellow no.4

LOT & EXP: 151008, 11/2014

GENTLE LAXATIVE			
bisacodyl tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0171
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BISACODYL (UNII: 10 X0 70 9 Y6 I) (BISACODYL - UNII:10 X0 70 9 Y6 I)	BISACODYL	5 mg	
Inactive Ingredients			
Ingredient Name	Strength		
ACACIA (UNII: 5C5403N26O)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			

STARCH, CORN (UNII: O8232NY3SJ)
GELATIN (UNII: 2G86QN327L)
HYPROMELLOSE PHTHALATE (24 % PHTHALATE, 55 CST) (UNII: 87Y6436BKR)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
POVIDONE (UNII: FZ989GH94E)
CALCIUM CARBONATE (UNII: H0G9379FGK)
SUCROSE (UNII: C151H8M554)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	BIS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0171-2	2 in 1 BOX		
1		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/15/2012	

Labeler - Kareway Product, Inc. (121840057)