

GENTLE LAXATIVE STIMULANT LAXATIVE- bisacodyl tablet, coated
Care One (American Sales Company)

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

Use

- for temporary relief of occasional constipation and irregularity
- this product generally produces a 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 pregnancy 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 | take 1 to 3 tablets in a single daily

over	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

- 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 (PEG) 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

Questions or comments?

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

Principal Display Panel

Compare to the Active Ingredient of Dulcolax® Laxative

Gentle Laxative

Bisacodyl 5 mg

GENTLE YET EFFECTIVE STIMULANT LAXATIVE
TABLETS

Enteric Coated

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

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by Foodhold U.S.A., LLC

LANDOVER, MD 20785

1-877-846-9949

Product Label

NDC 41520-019-25

CAREone®

Compare to the active ingredient in Dulcolax® Laxative†

GENTLE LAXATIVE

Bisacodyl 5 mg

GENTLE YET EFFECTIVE
STIMULANT LAXATIVE



Actual Size



25 TABLETS

Enteric Coated

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:
Exp. Date:

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Other information
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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
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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

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Bisacodyl USP 5 mg..... Stimulant laxative</p> <p>Purpose</p>		<p>Use</p> <ul style="list-style-type: none"> for temporary relief of occasional constipation and irregularly this product generally produces a bowel movement in 6 to 12 hours
<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>		<p>Warnings</p> <p>Do not use if you cannot swallow without chewing.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> stomach pain, nausea or vomiting a sudden change in bowel habits that lasts more
<p>Directions</p> <p>take with a glass of water</p> <p>adults and children 12 years of age and over take 1 to 3 tablets in a single daily dose</p> <p>children 6 to under 12 years of age take 1 tablet in a single daily dose</p> <p>children under 6 years of age ask a doctor</p>		

CareOne Gentle Laxative

GENTLE LAXATIVE STIMULANT LAXATIVE

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-019
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
SUCROSE (UNII: C151H8M554)	
POVIDONE (UNII: FZ989GH94E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	6 mm
Flavor		Imprint Code	TCL003
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-019-25	1 in 1 CARTON	09/30/2010	
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	09/30/2010	

Labeler - Care One (American Sales Company) (809183973)