STIMULANT LAXATIVE- bisacodyl tablet, delayed release RETAIL BUSINESS SERVICES, 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.

CARE ONE GENTLE LAXATIVE

Active ingredient

(In each tablet)

Bisacodyl 5mg

Purpose

Stimulant Laxative

Uses

- relieves 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)
- 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 1(800) 222-1222.

- 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: take 1 tablet in a single daily dose
- children under 6 years: ask a doctor

Inactive ingredients

Acadia, 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 Phthalates, Povidone, Shellac, Sodium Starch Glycolate, Stearic Acid, Sugar, Talc, Titanium Dioxide

Questions or comments?

1-888-333-9792

DISPLAY PANEL

GENTLE LAXATIVE BISACODYL 5 mg

GENTLE YET EFFECTIVE STIMULANT LAXATIVE

25 TABLETS

ENTERIC COATED





Enteric Coated

DISTRIBUTED BY: ADUSA DISTRIBUTION, LLC SALISBURY, NC 28147 For product questions or concerns, contact us at 1-833-992-3872 Quality guaranteed or your money back.

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

ORIG 03/21

STIMULANT LAXATIVE

bisacodyl tablet, delayed release

Product Information

Product Type HUMAN OTC DRUG NDC:72476-845 Item Code (Source)

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 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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
POVIDONE (UNII: FZ 989GH94E)	
SHELLAC (UNII: 46N107B710)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	5mm	
Flavor		Imprint Code	TCL003	
Contains				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:72476- 845-25	1 in 1 PACKAGE	03/30/2021				
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	03/30/2021		