

WOMENS LAXATIVE- bisacodyl tablet, coated
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 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 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	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:** magnesium 5 mg
- store between 20-25°C (68-77°F)

Inactive ingredients

acacia, calcium sulfate anhydrous, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D&C red # 27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, iron oxide, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

Questions or comments?

Call **1-888-333-9792**

Principal Display Panel

Compare to active ingredient of Dulcolax® Pink® Laxative*

Women's Gentle Laxative Tablets

Bisacodyl 5 mg

Stimulant laxative

Gentle, Overnight relief

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



WOMENS LAXATIVE

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-654
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)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

STARCH, CORN (UNII: O8232NY3SJ)
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
MAGNESIUM STEARATE (UNII: 70097M6I30)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
POVIDONE (UNII: FZ989GH94E)
SHELLAC (UNII: 46N107B710)
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)
STEARIC ACID (UNII: 4ELV7Z65AP)
SUCROSE (UNII: C151H8M554)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)
GELATIN (UNII: 2G86QN327L)
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	TCL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-654-25	25 in 1 CARTON	08/23/2019	
1		1 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	08/23/2019	

Labeler - RETAIL BUSINESS SERVICES, LLC (967989935)