

BISACODYL STIMULANT LAXATIVE- bisacodyl tablet, coated
Raritan Pharmaceuticals 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.

DRx. CHOICE® Stimulant Laxative 25 Coated Tablets

Active ingredient (in each tablet)

Bisacodyl, USP 5 mg

Purpose

Stimulant laxative

Use

- for 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

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

Stop use and ask a doctor if

- you have rectal bleeding or fail to have bowl 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 at (1-800-222-1222).

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 room temperature
- Protect from excessive humidity

Inactive ingredients

acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D&C yellow No. 10, FD&C yellow No. 6, 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?

1-866-467-2748

Principal Display Panel

NDC# **68163-116-25**

*Compare to the Active Ingredient in Dulcolax® Tablets

Bisacodyl Laxative

Bisacodyl, USP 5 mg/Stimulant Laxative

Gentle, Overnight relief constipation relief

25 Coated Tablets

*This product is not manufactured or distributed by Chattem Inc., the owner of the registered trademark Dulcolax® Tablets.

TAMPER EVIDENT: Do not use if any individual unit is broken or open.

IMPORTANT: Keep this carton for future reference on full labeling.

Manufactured by:
Raritan Pharmaceuticals
8 Joanna Court,
East Brunswick, NJ 08816



BISACODYL STIMULANT LAXATIVE

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-116
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, UNSPECIFIED (UNII: 2G86QN327L)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
RAW SUGAR (UNII: 8M707QY5GH)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	RP116
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-116-25	1 in 1 CARTON	10/29/2019	
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	10/29/2019	

Revised: 9/2023

Raritan Pharmaceuticals Inc