

BISACODYL 5MG- bisacodyl 5mg tablet, coated
Allegiant Health

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.

232 - Health A2Z Womans Laxative

Active Ingredient (in each tablet)

Bisacodyl USP 5mg

Purpose

Stimulant Laxative

Uses

- for relief of occasional constipation (irregularity)
- this product generally produces bowel movement in 6 to 12 hours

Warnings

Do not use

- if you are unable to swallow without chewing
- within 1 hour after taking an antacid or milk

Ask a doctor before use if you have

- abdominal pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks

When using this product

- do not chew or crush tablets
- abdominal discomfort, faintness, and cramps may occur

Stop use and ask a doctor if

- you need to use more than 1 week
- rectal bleeding or failure to have a bowel movement after use of a laxative.

These may be signs of a serious condition.

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. In case of accidental overdose, get medical help or contact a doctor or Poison Control Center (1-800-222-1222) right away.

Directions

- take with water

Adults and children 12 years of age and older: take 1 to 3 tablets in a single dose, once daily

Children 6 to 12 years of age: take 1 tablet once a day

Children under 6 years of age: consult a doctor

Other information

- store between 68° to 77°F (20° to 25°C)
- do not use blister unit is broken or torn

Inactive ingredients

acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow # 6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polyvinyl acetate phthalate, polydextrose, polyethylene glycol, propylparaben, propylene glycol, povidone, shellac glaze, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

Principal Display Panel

BISACODYL 5MG

bisacodyl 5mg tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-398
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 CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-398-92	1 in 1 CARTON	12/23/2014	
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	12/23/2014	

Labeler - Allegiant Health (079501930)

Revised: 3/2019

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