LAXATIVE ENTERIC COATED- bisacodyl 5mg tablet, sugar coated Allegiant Health

Assured 44-327

Active ingredient (in each tablet)

Bisacodyl USP 5 mg

Purpose

Stimulant Laxative

Uses

- for temporary relief of occasional constipation and irregularity
- this product generally produces 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
- you may have stomach discomfort, faintness and cramps

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative.
 These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

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 overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

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

Inactive ingredients

acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, 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



LAXATIVE ENTERIC COATED

bisacodyl 5mg tablet, sugar coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-404
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: 5C5403N260) **AMMONIA** (UNII: 5138Q19F1X) CALCIUM CARBONATE (UNII: H0G9379FGK) CARNAUBA WAX (UNII: R12CBM0EIZ) STARCH, CORN (UNII: 08232NY3SJ) D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) FD&C YELLOW NO. 6 (UNII: H77VEI93A8) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) FERROSOFERRIC OXIDE (UNII: XM0M87F357) ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) MAGNESIUM STEARATE (UNII: 70097M6I30) METHYLPARABEN (UNII: A2I8C7HI9T) POLYDEXTROSE (UNII: VH2XOU12IE) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MQ0SDW1A) **Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)** POVIDONE (UNII: FZ 989GH94E) PROPYLENE GLYCOL (UNII: 6DC9O167V3) PROPYLPARABEN (UNII: Z8IX2SC1OH) **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) **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) **DIMETHICONE** (UNII: 92RU3N3Y10)

Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	6mm	
Flavor		Imprint Code	5	
Contains				

ı	Packaging			
4	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168- 404-92	1 in 1 CARTON	03/25/2002	
]	-	25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69168- 404-03	250 in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2002	
13	NDC:69168- 404-32	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	03/25/2002	

Labeler - Allegiant Health (079501930)

Revised: 2/2019 Allegiant Health