BISACODYL - bisacodyl tablet, delayed release
Pharbest 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.

Drug facts

Active ingredient (in each tablet)
Bisacodyl 5 mg

Stimulant laxative

- 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)
- 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.

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 20 - 25^{0}C (68-77^{0}F)
- Protect from excessive humidity

Inactive ingredients: acacia, anhydrous lactose, beeswax, calcium sulfate, carnauba wax, colloidal silicon dioxide, corn starch, D&C yellow #10 lake, edible ink, FD&C yellow #6 lake, gelatin, iron oxide black, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, polyvinyl acetate phthalate, povidone, sodium starch glycolate, stearic acid, sugar, titanium dioxide

Questions?

Adverse drug event call: (866) 562-2756

BISACODYL

bisacodyl tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16103-367

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y6I) (BISACODYL - UNII:10X0709Y6I)	BISACODYL	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SHELLAC (UNII: 46N107B71O)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	S1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-367-17	25 in 1 BOTTLE, PLASTIC		
2	NDC:16103-367-08	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part334	01/25/2006	

Labeler - Pharbest Pharmaceuticals Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals Inc.		557054835	repack, relabel

Revised: 6/2012 Pharbest Pharmaceuticals Inc.