DULCOLAX STIMULANT LAXATIVE- bisacodyl tablet, coated
Chattem, 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.

Dulcolax Stimulant Laxative

Dulcolax Stimulant Laxative Tablets

Drug Facts

Active ingredient (in each tablet)

Bisacodyl (USP) 5 mg

Purpose

Stimulant laxative

Use

● for 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

● noticed 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 a 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

- contains FD&C Yellow No. 6
- do not use if individual blister unit is open or torn
- store at 20°-25°C (68°-77°F)
- protect from excessive humidity

Inactive ingredients

acacia senegal gum, 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 oxides, lactose, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

Questions?

Call **1-866-844-2798** or visit **www.Dulcolax.com**

Keep carton as it contains important product information.

PRINCIPAL DISPLAY PANEL

Dulcolax
LAXATIVE
50 TABLETS

DULCOLAX STIMULANT LAXATIVE

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41167-0200
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
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	ORANGE	**Score**	no score
Shape	ROUND	**Size**	5mm
Flavor		**Imprint Code**	DU
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0200-5	1 in 1 CARTON	02/25/2019	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-0200-6	8 in 1 CARTON	04/11/2019	
2		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41167-0200-8	3 in 1 CARTON	01/02/2019	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:41167-0200-3	2 in 1 CARTON	01/02/2019	
4		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:41167-0200-2	1 in 1 CARTON	02/15/2019	
5		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:41167-0200-1	1 in 1 CARTON	03/01/2019	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:41167-0200-4	4 in 1 CARTON	01/02/2019	
7		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	01/02/2019	

Labeler - Chattem, Inc. (003336013)

Revised: 1/2019 Chattem, Inc.