DULCOLAX STIMULANT LAXATIVE- bisacodyl tablet, coated Chattem, Inc.

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.

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Questions?

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PRINCIPAL DISPLAY PANEL

Dulcolax LAXATIVE 200 TABLETS



PRINCIPAL DISPLAY PANEL

Dulcolax LAXATIVE 50 TABLETS



DULCOLAX STIMULANT LAXATIVE

bisacodyl tablet, coated

Product Information					
Product Type	HUMAN OTC DR	RUG Item Code	(Source)	NDC:4116	57-0400
Route of Administration	ORAL				
Active Ingredient/Act	ive Moiety				
.	ngredient Name		Basis o	of Strength	Strengt
BISACODYL (UNII: 10X0709Y6	-		BISACODY	-	5 mg
Inactive Ingredients					
	Ingredien	t Name		S	strength
ACACIA (UNII: 5C5403N26O)	1100000705010				
	-				
CARNAUBA WAX (UNII: R12CI STARCH, CORN (UNII: 08232	· · ·				
FD&C YELLOW NO. 6 (UNII:					
D&C YELLOW NO. 10 (UNII:					
HYPROMELLOSE, UNSPECIF	· · ·	WO)			
FERRIC OXIDE RED (UNII: 1K					
LACTOSE, UNSPECIFIED FO	RM (UNII: J2B2A4N98	G)			
MAGNESIUM STEARATE (UN	II: 70097M6I30)				
METHYLPARABEN (UNII: A218	С7НІ9Т)				
POLYDEXTROSE (UNII: VH2X0	DU12IE)				
POLYETHYLENE GLYCOL, U		-			
Polyvinyl Acetate Phthalate		3)			
POVIDONE (UNII: FZ 989GH94					
PROPYLENE GLYCOL (UNII: 6					
PROPYLPARABEN (UNII: Z8IX					
SHELLAC (UNII: 46N107B710) SODIUM ALGINATE (UNII: C2					
SODIUM BENZOATE (UNII: O					
SODIUM BICARBONATE (UN	· -				
STEARIC ACID (UNII: 4ELV7Z)					
SUCROSE (UNII: C151H8M554					
TALC (UNII: 7SEV7J4R1U)					
TITANIUM DIOXIDE (UNII: 15	FIX9V2JP)				
TRIACETIN (UNII: XHX3C3X67	3)				
TRIETHYL CITRATE (UNII: 8Z	96QXD6UM)				
Product Characterist	ics				
Color	orange	Score		no score	
Shape	ROUND	Size		5mm	
Flavor		Imprint Code		DL	
Contains					

Pa	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167- 0400-5	1 in 1 CARTON	04/14/2019	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167- 0400-6	8 in 1 CARTON	04/14/2019	
2		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41167- 0400-8	3 in 1 CARTON	05/01/2019	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:41167- 0400-3	2 in 1 CARTON	04/14/2019	
4		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:41167- 0400-2	1 in 1 CARTON	04/14/2019	
5		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:41167- 0400-1	1 in 1 CARTON	04/14/2019	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:41167- 0400-4	4 in 1 CARTON	06/03/2019	
7		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:41167- 0400-9	1 in 1 CARTON	06/01/2022	
8		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
M	larketing	Information		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
от	C Monograph Dr	ug 505G(a)(3)	04/14/2019	

DULCOLAX STIMULA bisacodyl tablet, coated	NT LAXATIVE				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Sou	irce)	NDC:4116	7-0200
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingre	edient Name		Basis of S	trength	Strength

5 mg

Ingredient Name	Strength
ACACIA (UNII: 5C5403N260)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: 08232NY3SJ)	
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: Z8IX2SC10H)	
SHELLAC (UNII: 46N107B710)	
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	DL
Contains			

Packaging

#	ltem 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		5 in 1 BLISTER PACK; Type 0: Not a Combination roduct			
3	NDC:41167- 0200-8 3	in 1 CARTON	01/02/2019		
3		0 in 1 BLISTER PACK; Type 0: Not a Combination roduct			
4	NDC:41167- 0200-3 2	in 1 CARTON	01/02/2019		
4		5 in 1 BLISTER PACK; Type 0: Not a Combination roduct			
5	NDC:41167- 0200-2 1	in 1 CARTON	02/15/2019		
5		5 in 1 BLISTER PACK; Type 0: Not a Combination roduct			
6	NDC:41167- 0200-1 1	in 1 CARTON	03/01/2019		
6		0 in 1 BLISTER PACK; Type 0: Not a Combination roduct			
7	NDC:41167- 0200-4 4	in 1 CARTON	01/02/2019		
7		5 in 1 BLISTER PACK; Type 0: Not a Combination roduct			
Marketing Information					
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
		505G(a)(3)	01/02/2019		

Labeler - Chattem, Inc. (003336013)

Revised: 11/2023

Chattem, Inc.