DULCOLAX SIMULANT LAXATIVE- bisacodyl tablet, film coated
Chattem, Inc.

Dulcolax Stimulant Laxative CMP-CHA

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

● 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 gum, ammonium hydroxide, beeswax, carnauba wax, corn starch, D&C red #30 aluminum lake, D&C yellow #10 aluminum lake, glycerin, glyceryl monostearate, iron oxides, lactose monohydrate, magnesium stearate, methacrylic acid ethyl acrylate copolymer, methylparaben, modified starch, polyethylene glycol 6000, polysorbate 80, povidone, propylene glycol, propylparaben, shellac, sodium benzoate, sucrose, talc, titanium dioxide, triethyl citrate

Questions?

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

Keep carton as it contains important product information.

PRINCIPAL DISPLAY PANEL

OVERNIGHT RELIEF
Dulcolax
LAXATIVE
25 comfort coated Tablets

DULCOLAX SIMULANT LAXATIVE

bisacodyl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41167-0101
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)	
AMMONIA (UNII: 5138Q19F1X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	5mm
Flavor		**Imprint Code**	12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0101-0	1 in 1 CARTON	02/12/2021	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-0101-1	1 in 1 CARTON	02/12/2021	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41167-0101-2	1 in 1 CARTON	02/12/2021	
3		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:41167-0101-3	2 in 1 CARTON	02/12/2021	
4		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:41167-0101-4	4 in 1 CARTON	02/12/2021	
5		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:41167-0101-5	8 in 1 CARTON	02/12/2021	
6		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		

7	NDC:41167-0101-6	3 in 1 CARTON	02/12/2021	
7		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:41167-0101-7	1 in 1 CARTON	06/01/2022	
8		6 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 Drug	505G(a)(3)	02/12/2021	

Labeler - Chattem, Inc. (003336013)

Revised: 11/2023 Chattem, Inc.