

DULCOLAX - bisacodyl tablet, coated

Physicians Total Care, 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 ® Tablets

Drug Facts

Active ingredient (in each tablet)	Purpose
Bisacodyl USP 5 mg	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)
- 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 2 years of age	ask a doctor

Other information

- store at 20-25°C (68-77°F)
- protect from excessive humidity

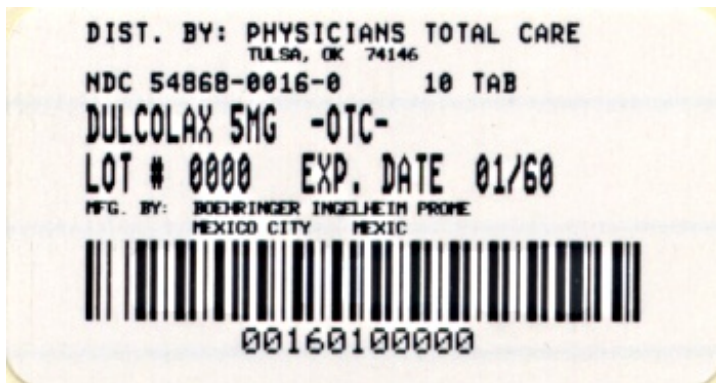
Inactive ingredients

acacia, acetylated monoglyceride, carnauba wax, cellulose acetate phthalate, corn starch, dibutyl phthalate, docusate sodium, gelatin, glycerin, iron oxides, kaolin, lactose, magnesium stearate, methylparaben, pharmaceutical glaze, polyethylene glycol, povidone, propylparaben, Red No. 30 lake, sodium benzoate, sorbitan monooleate, sucrose, talc, titanium dioxide, white wax, Yellow No. 10 lake

Dulcolax (bisacodyl USP) laxative tablets

5 mg

NDC 54868-0016-0



DULCOLAX

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-0016(NDC:0597-0012)
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)	
carnauba wax (UNII: R12CBM0EIZ)	

cellacefate (UNII: F2O5O2O19F)	
starch, corn (UNII: O8232NY3SJ)	
dibutyl phthalate (UNII: 2286E5R2KE)	
docosate sodium (UNII: F05Q2T2JA0)	
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
kaolin (UNII: 24H4NWX5CO)	
lactose (UNII: J2B2A4N98G)	
magnesium stearate (UNII: 70097M6I30)	
methylparaben (UNII: A2I8C7HI9T)	
shellac (UNII: 46N107B71O)	
polyethylene glycol (UNII: 3WJQ0SDW1A)	
povidone (UNII: FZ989GH94E)	
propylparaben (UNII: Z8IX2SC1OH)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitan monooleate (UNII: 06XEA2VD56)	
sucrose (UNII: C151H8M554)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	
white wax (UNII: 7G1J5DA97F)	

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:54868-0016-0	1 in 1 CARTON		
1		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/19/2010	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel