DULCOLAX- bis acodyl tablet, coated Mechanical Servants, 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®

Drug Facts

Active ingredient (in each tablet)

Bisacodyl USP 5 mg

Purpose

Stimulant laxative

Use

- 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)
- do not use within 1 hour after taking an antacid or milk
- it may cause stomach discomfort, faintness and cramps

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 and	1 to 3 tablets in a single daily dose
over	1 to 5 tablets in a single daily dose
children 6 to under 12 years of age	1 tablet in a single daily dose

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

Questions

1-888-285-9159 (English/Spanish)

Or visit www.DULCOLAX.com

Repackaged and distributed by Convenience Valet® Melrose Park, IL 60160

PRINCIPAL DISPLAY PANEL - 5 mg Pouch Package

CONVENIENCE

 \mathbf{CV}

VALET®

DRINKING CUP INCLUDED

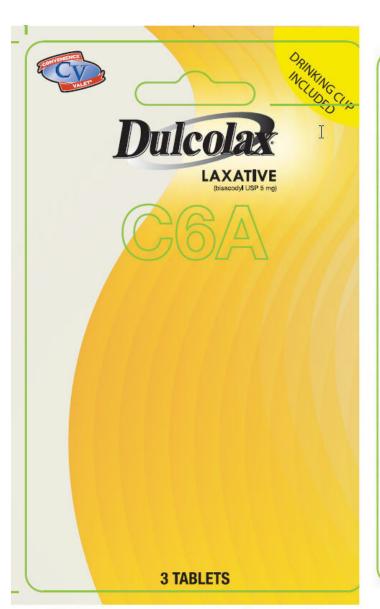
 $Dulcolax^{
m ext{ iny R}}$

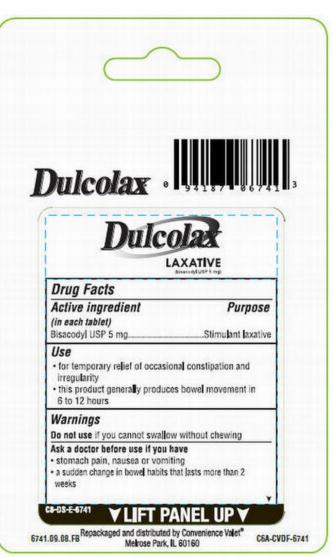
LAXATIVE

(bisacodyl USP 5 mg)

C6A

3 TABLETS







Drug Facts (continued)

wnen using this product . do not chew or crush tablet(s) · do not use within 1 hour after taking an antacid or milk it may cause stomach discomfort, faintness and cramps 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 Keep out of reach of children hease of overdose, get medical help or contact a Poison Control Center right Directions take with a glass of water 1 to 3 tablets in a single adults and children 12 years and over 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

Hinge

Hinge

Drug Facts (continued)

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, kapin Dlactosa, 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

Questions 1-888-285-9159 (English/Spanish) Or visit www.DULCOLAX.com

Individually sealed. Do not use if seal is broken.

DULCOLAX does not supply store brands.

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DULCOLAX

bisacodyl tablet, coated

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:29485-6741(NDC:0597-0012)

Route of Administration ORAL

Active Ingredient/Active Moiety

11011/6 1118/1011011011/6 1/10101/				
Ingredient Name	Basis of Strength	Strength		
bisacodyl (UNII: 10 X0709 Y6 I) (bisacodyl - UNII:10 X0709 Y6 I)	bisacodyl	5 mg		

Ingredient Name	Strength
acacia (UNII: 5C5403N26O)	
carnauba wax (UNII: R12CBM0EIZ)	
cellacefate (UNII: F2O5O2OI9F)	
starch, corn (UNII: O8232NY3SJ)	
dibutyl phthalate (UNII: 2286E5R2KE)	
docusate sodium (UNII: F05Q2T2JA0)	
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
kaolin (UNII: 24H4NWX5CO)	
lactose (UNII: J2B2A4N98G)	
magnesium stearate (UNII: 70097M6I30)	
methylparaben (UNII: A218 C7H19 T)	
shellac (UNII: 46N107B71O)	
polyethylene glycols (UNII: 3WJQ0SDW1A)	
povidone (UNII: FZ989GH94E)	
propylparaben (UNII: Z8IX2SC1OH)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitan monooleate (UNII: 06XEA2VD56)	
sucrose (UNII: C151H8 M554)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	
white wax (UNII: 7G1J5DA97F)	
diacetylated monoglycerides (UNII: 5Z17386USF)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics			
Color	ORANGE	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	12;BI
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:29485-6741-3	1 in 1 PACKAGE		
1	3 in 1 POUCH		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part334	0 1/0 1/20 10		

Establishment			
Name	Address	ID/FEI	Business Operations
Boehringer Ingelheim Promeco S.A. de C.V.		8 12 5 7 9 4 7 2	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Mechanical Servants, Inc.		005530951	RELABEL

Revised: 1/2012 Mechanical Servants, Inc.