

LAXATIVE- bisacodyl tablet, coated
Freds 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.

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

take 1 to 2 tablets in a single daily

adults and children 12 years of age and over	take 1 to 3 tablets in a single daily dose
children 6 to under 12 years of age	take 1 tablet in a single daily dose
children under 6 years of age	ask a doctor

Other information

- store between 20°-25°C (68°-77°F)

Inactive ingredients

acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, iron oxide, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, and titanium dioxide

Questions or Comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Laxative Tablets

Bisacodyl, 5 mg

Gentle, Predictable Overnight Relief From Constipation

Enteric coated tablets

Compare to the active ingredient in: Dulcolax®*

*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, inc., distributor of Dulcolax® Laxative.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: fred's Inc.

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

Product Label



mg
e Tablets

Laxative Tablets

Bisacodyl, 5 mg

Gentle, Predictable
Overnight Relief
From Constipation

25 Enteric
Coated Tablets



Compare to the
active ingredient in:
Dulcolax®*

TAMPER EVIDENT: DO NOT USE IF CARTON UNIT IS TORN, BROKEN OR SHOWS AN

KEEP OUTER CARTON FOR COMPLETE WARNING

Lot No.:
Exp. Date:

*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor of Dulcolax® Laxative.

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fred's Promise
Not Happy With This Product?
Just Bring It Back For a Refund!

PLD-E23J
FC002037



<p>Drug Facts Active ingredient (in each tablet) Bisacodyl USP 5 mg.....Stimulant laxative</p>		<p>Use ■ for temporary relief of occasional constipation and irregularity ■ this product generally produces a bowel movement in 6 to 12 hours</p>	
<p>Purpose Control Center right away. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>		<p>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</p>	
<p>Directions ■ take with a glass of water adults and children 12 years of age and over take 1 to 3 tablets in a single daily dose children 6 to under 12 years of age take 1 tablet in a single daily dose children under 6 years of age ask a doctor</p>		<p>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, flatness and cramps</p>	
<p>Other information ■ store between 20°-25°C (68°-77°F)</p>		<p>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.</p>	
<p>Drug Facts (continued)</p>		<p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	
<p>Inactive ingredients acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, iron oxide, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide</p>			

Fred's Laxative tablets

LAXATIVE

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55315-190
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (BISACODYL)	BISACODYL	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA	
CALCIUM SULFATE ANHYDROUS	
ANHYDROUS LACTOSE	
CARNAUBA WAX	
SILICON DIOXIDE	
STARCH, CORN	
D&C YELLOW NO. 10	
FD&C YELLOW NO. 6	
ALUMINUM OXIDE	
GELATIN	
FERRIC OXIDE RED	
FERROSFERRIC OXIDE	
FERRIC OXIDE YELLOW	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOL 400	
Polyvinyl Acetate Phthalate	
POVIDONES	
SHELLAC	
SODIUM STARCH GLYCOLATE TYPE A CORN	
STEARIC ACID	
TALC	
TITANIUM DIOXIDE	
SUCROSE	

Product Characteristics

Color	ORANGE, YELLOW	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	TCL003
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:55315-190-03	1 in 1 CARTON		
1		25 in 1 BLISTER PACK; Combination Product Type = C112160		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	07/08/2010	

Labeler - Freds Inc (005866116)

Revised: 10/2014

Freds Inc