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 enteric coated 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)
- 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	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 at controlled room temperature 15º- 30º C (59º- 86º 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 (iron oxide ochre), 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 toll free: **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

*Compare to the active ingredient in DULCOLAX®

*This product is not manufactured or distributed by Boehringer Ingelheim Consumer Healthcare Products, owner of the registered trademark Dulcolax®

LAXATIVE TABLETS

Bisacodyl, USP 5 mg

Gentle, Predictable Overnight relief from constipation

EACH TABLET IS INDIVIDUALLY SEALED IN A BLISTER PACK. DO NOT USE IF BLISTER FOIL IS BROKEN.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

fred's

Laxative Tablets

Bisacodyl, USP 5 mg

NDC 55315-190-03

Actual Size

Laxative Tablets

Bisacodyl, USP 5 mg

Gentle, Predictable Overnight Relief From Constipation

fred's LAB TESTED
Lab Tested for Quality, Fred Tested for Satisfaction

Compare to the active ingredient in: Dulcolax®*

25 Enteric Coated Tablets

EACH TABLET IS INDIVIDUALLY SEALED IN A BLISTER PACK. DO NOT USE IF BLISTER FOIL IS BROKEN.

PLD-D F19FR25

Lot No.:

Exp. Date:

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

*This product is not manufactured or distributed by Boehringer Ingelheim Consumer Health Care Products, owner of the registered trademark Dulcolax®.

Drug Facts (continued)

(PEG) 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, and titanium dioxide

Questions or comments?

Call Toll Free: **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Drug Facts

Active Ingredient (in each enteric coated tablet) — **Purpose**

Bisacodyl, USP 5 mg ..... Stimulant laxative

Use
- for temporary relief of occasional constipation and irregularity
- this product generally produces a 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	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 at controlled room temperature 15°-30°C (59°-86°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 (iron oxide ochre), magnesium stearate, microcrystalline cellulose, polyethylene glycol

DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD, MEMPHIS, TN 38118
www.fredsinc.com

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

0 84579 21022 0

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Drug Facts

Bisacodyl 5 mg 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	
FERROSOFERRIC 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
1	NDC:55315-190-03	1 in 1 CARTON		
1		25 in 1 BLISTER PACK		

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)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 2/2013 Freds Inc