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 20º-25ºC (68º-77ºF)

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

Laxative Tablets

Bisacodyl, 5 mg

Gentle, Predictable Overnight Relief From Constipation

25 Enteric Coated Tablets

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

Compare to the active ingredient in: Dulcolax®*

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

KEEP OUTER CARTON FOR COMPLETE WARNIN

Lot No.:
Exp. Date:

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4300 NEW GETWELL RD, MEMPHIS, TN 38118
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fred's Promise
Not Happy With This Product?
Just Bring It Back For a Refund!

PLD-E23J
FC002037

0 84579 21022 0

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Fred's Laxative tablets

LAXATIVE
bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55315-190
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)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
GELATIN (UNII: 2G86QN327L)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONES (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SUCROSE (UNII: C151H8M554)	

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; Type 0: Not a Combination Product		

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