

**WOMENS GENTLE LAXATIVE- bisacodyl tablet, coated
FRED'S, 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.

Freds 44-326-Delisted

Active ingredient (in each enteric coated tablet)

Bisacodyl 5 mg

Purpose

Stimulant laxative

Uses

- for gentle, overnight relief of occasional constipation (irregularity)
- this product generally produces bowel movement in 6 to 12 hours

Warnings

Do not use

- in children under 6 years of age
- in persons who cannot swallow without chewing

Ask a doctor before use if you have

- abdominal pain
- nausea
- vomiting
- sudden change in bowel movements that persist over a period of 2 weeks

When using this product

- do not use for a period longer than 1 week unless directed by a doctor
- you may experience abdominal discomfort, faintness and cramps

Stop use and ask a doctor if

- rectal bleeding occurs
- you fail to have a bowel movement

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

- do not chew or crush tablets
- do not take within 1 hour after taking an antacid or milk

adults and children over 12 years of age	oral dosage is 1 to 3 tablets in a single or divided daily dose
children 6 to under 12 years of age	oral dosage is 1 tablet in a single daily dose
children under 6 years of age	ask a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- see end flap for expiration date and lot number

Inactive ingredients

acacia, black iron oxide, calcium carbonate, carnauba wax, corn starch, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, lactose, magnesium stearate, methylparahydroxy benzoate, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparahydroxy benzoate, shellac glaze, silica, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

Principal Display Panel

FRED'S®

Stimulant Laxative

Women's

Gentle Laxative

Bisacodyl 5 mg

Gentle, Dependable Overnight Relief

30 Enteric Coated Tablets

Tested Against The Active Ingredient In: **CORRECTOL®***

*This product is not manufactured or distributed Schering-Plough Healthcare Products, owner of the registered trademark Correctol®.

50844 REV0410E32601

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

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Drug Facts (continued)

Warnings ■ in children under 6 years of age ■ in persons who cannot swallow without chewing ■ do not use ■ do not chew or crush tablets or milk

Ask a doctor before use if you have ■ abdominal pain ■ nausea ■ vomiting ■ sudden change in bowel movements that persists over a period of 2 weeks ■ do not use for a period longer than 1 week unless directed by a doctor

When using this product ■ you may experience abdominal discomfort, flatness and cramps ■ rectal bleeding occurs ■ you fail to have a bowel movement

Stop use and ask a doctor if

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Inactive ingredients acacia, ammonium lactate, FD&C yellow #6 aluminum lake, hypromellose, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, camouba wax, colloidal silicon dioxide, corn starch, hydroxide, black iron oxide, calcium carbonate.

Other information ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ protect from excessive moisture ■ see end flap for expiration date and lot number

Directions ■ do not take within 1 hour after taking an antacid or milk

adults and children over 12 years of age	oral dosage is 1 to 3 tablets in a single or divided daily dose
children 6 to under 12 years of age	oral dosage is 1 tablet in a single daily dose
children under 6 years of age	ask a doctor

Drug Facts (continued)

Drug Facts

Active ingredient (in each enteric coated tablet) Bisacodyl 5 mg, Stimulant laxative

Purpose ■ for gentle, overnight relief of occasional constipation (irregularity) ■ this product generally produces bowel movement in 6 to 12 hours

Uses

Drug Facts (continued)

B-0510-326-01 REV0412G32601

fred's

Stimulant Laxative

Actual Size

Women's Gentle Laxative

Bisacodyl 5 mg

Gentle, Dependable Overnight Relief

30 Enteric Coated Tablets

LAB TESTED
Lab Tested for Quality, Fred Tested for Satisfaction

Compare to the active ingredient in: **Correctol**®

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!

OMT C

Drug Facts (continued)

This product is not manufactured or distributed by MSD Consumer Care, Inc., owner of the registered trademark Correctol®.

sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate, phtalate, povidone, polyethylene glycol, propylparahydroxy benzoate, shellac glaze, simethicone, sodium alginate, lactose, magnesium stearate, methylparahydroxy benzoate, polydextrose, polyethylene glycol, polyvinyl acetate

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

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WOMENS GENTLE LAXATIVE

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-326
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0709Y6I) (BISACODYL - UNII:10 X0709 Y6I)	BISACODYL	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	44;326
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-326-01	1 in 1 CARTON		
1		30 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	02/12/2005	12/14/2018

Labeler - FRED'S, INC. (005866116)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(55315-326)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55315-326)

Revised: 1/2016

FRED'S, INC.