WOMENS GENTLE LAXATIVE- bis acodyl 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

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
Bis acodyl 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

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

If pregnant or breast-feeding, ask a health

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

Stop use and ask a doctor if

and cramps

- Non wsy experience abdominal discomfort, faintness directed by a doctor
 - do not use for a period longer than 1 week unless When using this product

over a period of 2 weeks

- sudden change in bowel movements that persists
 - gnitimov sesuen nisq lanimobds Ask a doctor before use if you have
- IU DELZOUZ MUO CSUUOI ZMSIJOM MILIONI CUEMIUB ■ in children under 6 years of age Do not use Warnings

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Active ingredient

Drug Facts

B-0510-326-01 REV0412G32601

Bisacodyl 5 mg. Stimulant laxative (in each enteric coated tablet)

Purpose

RETAIN CARTON FOR COMPLETI

 this product generally produces bowel movement in couzgbsgou (ittegularity) ■ for gentle, overnight relief of occasional

lake, FD&C yellow #6 aluminum lake, hypromellose,

carnauba wax, colloidal silicon dioxide, corn starch,

hydroxide, black iron oxide, calcium carbonate,

Inactive ingredients acacia, ammonium

D&C red #27 aluminum lake, FD&C blue #2 aluminum

■ store at 25°C (77°F); excursions permitted between

SSK S GOCTOF

adults and children oral dosage is 1 to 3 tablets in

do not take within 1 hour after taking an antacid or

single daily dose

oral dosage is 1 tablet in a

■ do not chew or crush tablets

a single or divided daily dose

Other information

6 years of age

children under

12 years of age

Directions

8 to 12 hours

children 6 to under

over 12 years of age

■ see end flap for expiration date and 12°-30°C (59°-86°F) ■ protect from excessive

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Drug Facts (continued)

PRODUCT INFORMATION

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Stimulant Laxative

Actual Size



Women's

Gentle Laxative

Bisacodyl 5 mg Gentle, Dependable Overnight Relief



Compare to the active ingredient in: Correctol**



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

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30 Enteric Coated Tablets

20844 HEAD412632601

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

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

Orng Facts (continued)

WOMENS GENTLE LAXATIVE

bisacodyl tablet, coated

Product Information

Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:55315-326

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			
FERROSOFERRIC OXIDE			
CALCIUM CARBONATE			
CARNAUBA WAX			
D&C RED NO. 27			
FD&C BLUE NO. 2			
FD&C YELLOW NO. 6			
HYPROMELLOSES			
LACTOSE			
MAGNESIUM STEARATE			
POLYDEXTROSE			
POLYETHYLENE GLYCOLS			
Polyvinyl Acetate Phthalate			
POVIDONES			
PROPYLENE GLYCOL			
SO DIUM ALGINATE			
SO DIUM BENZO ATE			
SO DIUM BICARBO NATE			
STEARIC ACID			
SUCROSE			
TALC			
TITANIUM DIO XIDE			
TRIACETIN			
TRIETHYL CITRATE			

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		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part334	02/12/2005		

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: 3/2013 FRED'S, INC.