# WOMANS LAXATIVE- bis acodyl tablet, coated Shopko Stores Operating Co., LLC.

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.

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#### **DRUG FACTS**

# Active ingredient (in each enteric coated tablet)

Bisacodyl 5mg

## Purpose

Stimulant laxative

#### Use

• for relief of occasional constipation and irregularity. This product generally produces bowel movement within 8 to 12 hours if taken at bedtime or within 6 hours if taken before breakfast.

# Warnings

#### Do not use

- if you are currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for longer than 1 week, unless directed by a doctor. Prolonged or continued use of this product can lead to laxative dependency and loss of normal bowel function. Serious side effects from prolonged use or overdose can occur

#### Caution

- do not chew or crush
- do not give to children under 6 years of age or to persons who cannot swallow without chewing
- do not take this product within 1 hour after taking an antacid and/or milk
- this product may cause abdominal discomfort, faintness, rectal burning, and mild cramps

## Ask a doctor before use if

• you notice a sudden change in bowel habits that persists over a period of 2 weeks.

# Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use of a laxative

### 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 take more than 3 tablets daily

adults and children 12 years of age and older take 1-3 tablets in a single dose once daily children 6 to under 12 years of age take 1 tablet daily children under 6 years of age to consult a doctor

#### Other information

- each tablet contains: calcium 15 mg/tablet
- store at 15°-30°C (59°-86°F)
- keep in a dry place
- \*This product is not manufactured or distributed by Schering-Plough, owner of the registered trademark Correctol®.

# **Inactive ingredients**

acacia, calcium sulfate anhydrous, carnauba wax, colloidal silicon dioxide, corn starch, D&C Red #7 Calcium Lake, hypromellose phthalate, iron oxide, iron oxide Black, iron oxide Yellow, kaolin, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide, and triacetin

# **Principal Display Panel**

Woman's Laxative Tablets
Stimulant Laxative for gentle, dependable overnight relief
Bisacodyl, 5 mg Tablets
\*Compare to Correctol® Active ingredient
Call toll free 1-877-753-3935
TAMPER EVIDENT
USE ONLY IF BLISTERS ARE INTACT.

### PRODUCT LABEL



#### WOMANS LAXATIVE TABLETS

## WOMANS LAXATIVE bisacodyl tablet, coated **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:37012-120 ORAL Route of Administration

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)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO.7 (UNII: ECW0LZ41X8)	
HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST) (UNII: 87Y6436BKR)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
KAOLIN (UNII: 24H4NWX5CO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONES (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B710)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8 M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics				
Color	PINK	Score	no score	
Shape	ROUND	Size	11mm	
Flavor		Imprint Code	TCL057	
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:37012-120-30	2 in 1 CARTON		
1	15 in 1 BLISTER PACK		

<b>Marketing Informat</b>	ion		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

07/09/2010

Labeler - Shopko Stores Operating Co., LLC. (023252638)

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

Revised: 3/2013

Shopko Stores Operating Co., LLC.