## GENTLE LAXATIVE WOMENS- bisacodyl tablet, coated L.N.K. International, 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.

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## **Quality Plus 44-676**

## Active ingredient (in each tablet)

Bisacodyl 5 mg

#### **Purpose**

Stimulant laxative

#### Uses

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

### **Warnings**

#### Do not use

if you are unable to swallow without chewing.

### Ask a doctor before use if you have

- abdominal pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks

## When using this product

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

#### Stop use and ask a doctor if

rectal bleeding or failure to have a bowel movement occurs after use of a laxative. These may be signs of a serious condition.

## 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 (1-800-222-1222) right away.

#### Directions

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

- adults and children 12 years and over: take 1 to 3 tablets in a single dose, once daily
- children under 12 years: ask a doctor

### Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

## **Inactive ingredients**

anhydrous lactose, carmine, colloidal silicon dioxide, corn starch, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, methacrylic acid, polydextrose, polyethylene glycol, shellac wax, simethicone, sodium bicarbonate sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

#### Questions or comments?

[1-800-426-9391]

## Principal display panel

QUALITY + PLUS

NDC 50844-676-01

\*Compare to active ingredient in Correctol®

WOMEN'S

#### **GENTLE LAXATIVE**

Bisacodyl 5 mg •STIMULANT LAXATIVE

Gentle, dependable overnight relief

30 Tablets

ENTERIC COATED ACTUAL SIZE

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

\*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Correctol<sup>®</sup>.

50844 ORG051567601

Distributed by

LNK INTERNATIONAL, INC.

60 Arkay Drive Hauppauge, NY 11788 USA



Walgreens 44-676

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50844-676
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

Inactive Ingredients	
Ingredient Name	Strength
ANHYDRO US LACTO SE (UNII: 3S Y5LH9 PMK)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
SHELLAC (UNII: 46N107B71O)	
WATER (UNII: 059QF0KO0R)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	

Product Characteristics				
Color	PINK	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	В	
Contains				

]	Packaging			
7	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:50844-676-01	2 in 1 CARTON	09/16/2015	
1		15 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	09/16/2015			

## Labeler - L.N.K. International, Inc. (038154464)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(50844-676)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(50844-676)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	PACK(50844-676)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	PACK(50844-676)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(50844-676)

Revised: 10/2019 L.N.K. International, Inc.