

WOMENS GENTLE LAXATIVE- bisacodyl tablet, delayed release
Topco Associates, LLC

Topcare 44-676A-Womens Laxative-Delisted

Active ingredient (in each tablet)

Bisacodyl USP, 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 cannot swallow without chewing.

Ask a doctor before use if you have

- a sudden change in bowel habits that lasts more than 2 weeks
- stomach pain, nausea or vomiting

When using this product

- do not chew or crush tablet(s)
- do not use within 1 hour after taking an antacid or milk
- you may have stomach discomfort, faintness and cramps

Stop use and ask a doctor if

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

adults and children 12 years and over	take 1 to 3 tablets in a single daily dose
children 6 to under 12 years	take 1 tablet in a single daily dose
children under 6 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°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number
- avoid excessive humidity

Inactive ingredients

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

Questions or comments?

1-888-423-0139

Principal Display Panel

+TopCare®
health

NDC 36800-676-01

**Women's Gentle
Laxative**

BISACODYL USP 5 mg • STIMULANT LAXATIVE

**Gentle, Dependable, Relief
from Constipation**

**30 ENTERIC COATED
TABLETS**

actual size

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

50844 REV011967601

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QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com

Visit here for more information: <http://topbrnds.com/48ZZSE>

QUALITY GUARANTEED

B9991R1

Drug Facts (continued)

Warnings
Do not use if you cannot swallow without chewing.
Ask a doctor before use if you have
■ a sudden change in bowel habits that lasts more than 2 weeks
■ stomach pain, nausea or vomiting
When using this product
■ do not chew or crush tablet(s)
■ do not use within 1 hour after taking an antacid or milk
■ you may have stomach discomfort, flatness and cramps
Stop use and ask a doctor if
■ you have rectal bleeding or fail to have a bowel movement after use of a laxative. 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.

Drug Facts (continued)

Other information
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■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ avoid excessive humidity
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Inactive ingredients carmine, colloidal silicon dioxide, corn starch, FD&C red #40 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, stearic acid, sodium bicarbonate, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, tracefin, triethyl citrate

Drug Facts (continued)

Directions ■ take with a glass of water
adults and children 12 years and over
take 1 to 3 tablets in a single daily dose
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Drug Facts (continued)

Active ingredient
(in each tablet)
Bisacodyl USP, 5 mg..... Stimulant laxative

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Drug Facts (continued)

B-1910-676A-01-R
REV0119A67601



NDC 36800-676-01

Women's Gentle Laxative

BISACODYL USP 5 mg • STIMULANT LAXATIVE

Gentle, Dependable, Relief from Constipation

30 ENTERIC COATED TABLETS



actual size

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

Do not print Area Lot & Exp. Date

QUALITY GUARANTEED

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50844 REV0119A67601

Drug Facts (continued)

Questions or comments? 1-888-423-0139

TopCare 44-676A



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bisacodyl tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-676
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SHELLAC (UNII: 46N107B710)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-676-01	2 in 1 CARTON	05/01/2019	03/31/2026

1	15 in 1 BLISTER PACK; Type 0: Not a Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	05/01/2019	03/31/2026

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(36800-676)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(36800-676) , pack(36800-676)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(36800-676)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(36800-676)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(36800-676)