

LAXATIVE- bisacodyl tablet, delayed release
TOPCO ASSOCIATES LLC

TopCare 44-676A-Gentle Laxative

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
- it may cause 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

- **do not take more than directed**
- 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°-30°C (59°-86°F)
- avoid excessive humidity
- see end flap for expiration date and lot number

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 76162-676-01

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 REV0923B67601

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ITASCA, IL 60143
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com

QUALITY GUARANTEED

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
 ■ it may cause 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.

Drug Facts (continued)

Other information
 ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BUSTER IS TORN OR BROKEN
 ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ avoid excessive humidity
 ■ see end flap for expiration date and lot number
Inactive ingredients
 carmine, colloidal silicon dioxide, corn starch, FD&C red #40 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, methacrylic acid, microcrystalline

Drug Facts (continued)

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

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

Uses
 ■ take with a glass of water
 ■ do not take more than directed
 ■ take 1 to 3 tablets in a single daily dose
 ■ take 1 tablet in a single daily dose
 ■ children 6 to under 12 years
 ■ children under 6 years ask a doctor



Gentle Laxative

BISACODYL USP 5 mg • STIMULANT LAXATIVE
 Gentle, Dependable, Relief from Constipation

30 ENTERIC COATED TABLETS



actual size



9

B-19110-676A-01-GL
 REV0923867601

NDC 76162-676-01

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

No Print / No Varnish
 Lot no. & Exp. date

Scan here for more information or call 1-888-423-0139



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 www.topcarebrand.com
QUALITY GUARANTEED

Drug Facts (continued)
 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

TopCare 44-676A

LAXATIVE

bisacodyl tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-676
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 ALUMINUM LAKE (UNII: 6T47AS764T)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
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

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-676-01	2 in 1 CARTON	04/20/2024	
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 Drug	505G(a)(3)	04/20/2024	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(76162-676)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(76162-676) , pack(76162-676)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(76162-676)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(76162-676)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(76162-676)

Revised: 4/2025

TOPCO ASSOCIATES LLC