

LAXATIVE- bisacodyl tablet, delayed release
TOPCO ASSOCIATES LLC

TopCare 44-676A

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

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
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, 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)

Inactive ingredients
 carmine, colloidal silicon dioxide, corn starch, FD&C red #40 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, methacrylic acid, microcrystalline

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

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

Drug Facts
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

Drug Facts (continued)



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 BUSTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

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

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

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B-19110-676A-01-GL
 REV0923867601

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 |
|--|--|------------------------|----------------------|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76162-676-01 | 2 in 1 BOX | 04/20/2024 | |
| 1 | | 30 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: 4/2024

TOPCO ASSOCIATES LLC