LAXATIVE- bisacodyl tablet, delayed release Chain Drug Marketing Association, Inc.

Quality Choice 44-327

Active ingredient (in each tablet)

Bisacodyl USP, 5 mg

Purpose

Stimulant laxative

Uses

- for relief of occasional constipation and 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 use within 1 hour after taking an antacid or milk
- do not chew or crush tablet(s)
- 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	take 1 to 3
children	tablets
12 years and	in a single daily
over	dose
children 6 to	take 1 tablet in
under	a single
12 years	daily dose
children under	ask a doctor
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

acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac glaze, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-426-9391

Principal Display Panel NDC 83324-061-30

QC_® QUALITY CHOICE

*Compare to the Active Ingredient in Dulcolax® Laxative Tablets

Laxative

Bisacodyl USP, 5 mg - Stimulant Laxative

Gentle, Dependable Constipation Relief

Actual Size

25 Comfort Coated Tablets

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

SATISFACTION GUARANTEED 100% QC®

Distributed by CDMA, Inc. Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2362

*This product is not manufactured or distributed by A. Nattermann & Cie. GmbH, owner of the registered trademark Dulcolax® Laxative Tablets.

50844 REV0923B32756

*This product is not manufactured or distributed by A. Nattermann & Cie. GmbH, owner of the registered trademark Dulcolax® Laxative Tablets.

REV0923B32756

25 Comfort Coated Tablets



Constipation Relief Gentle, Dependable

Bisacodyl USP, 5 mg - Stimulant Laxative

Sylistive

Dulcolax® Laxative Tablets Active Ingredient in Compare to the



Distributed by CDMA, Inc. Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2362

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



Bisacodyl USP, 5 mg - Stimulant Laxative

Overnight Relief



Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Purpose

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

. Stimulant laxative

Uses

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

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
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding, ask a health professional

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

- do not take more than directed

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 acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac glaze, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

No Print/No Varnish

Lot & EXP

B-0220-327-56-BLR REV0923832756

Quality Choice 44-327

LAXATIVE

bisacodyl tablet, delayed release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83324-061

Route of Administration ORAL

Active Ingredient/Active Moiety

	•	-	-			
		Ingre	dient Name		Basis of Strength	Strength
ICACODVI	(LINIII: 10YO	1700V6I) (DE	ACETYL BIS ACODYL		RIS ACODYI	5 ma

Inactive Ingredients	
Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
AMMONIA (UNII: 5138Q19F1X)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B710)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

SUCROSE (UNII: C151H8M554)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TRIACETIN (UNII: XHX3C3X673)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	5
Contains			

Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
NDC:83324- 061-30	1 in 1 BOX	04/26/2024					
1	25 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)	04/26/2024				

Labeler - Chain Drug Marketing Association, Inc. (011920774)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		038154464	manufacture(83324-061) , pack(83324-061)		

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(83324-061) , pack(83324-061)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(83324-061)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(83324-061)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(83324-061)

Revised: 4/2024

Chain Drug Marketing Association, Inc.