GENTLE LAXATIVE- bisacodyl tablet, delayed release Strategic Sourcing Services, LLC (Sunmark)

Sunmark 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

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

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	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

Questions or comments?

1-800-426-9391

Principal display panel

sunmark®

COMPARE TO DULCOLAX® LAXATIVE TABLETS ACTIVE INGREDIENT*

NDC 49348-032-05

gentle laxative

BISACODYL USP, 5 mg stimulant laxative

gentle, dependable constipation relief

COMFORT COATED

ACTUAL SIZE

25 TABLETS

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 Sanofi-Aventis Deutschland GMBH, owner of the registered trademark Dulcolax® Laxative Tablets. 50844 REV0119B32756

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NDC 49348-032-05

<mark>sun</mark>mark°

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Monday-Friday

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Questions or comments?

Drug Facts (continued)

pranium dioxide, triacetin, triethy citrate sodium bicarbonate, stearic acid, sucrose, talc, simethicone, sodium alginate, sodium benzoate, bropylene glycol, propylparaben, shellac glaze, di)col, polyvinyl acetate phthalate, povidone,

Drug Facts (continued)

REV0119B32756 B-1242-327-56

> ■ you need to use a laxative for more than 1 week sidus of a serious condition. movement after use of a laxative. These could be ■ you have rectal bleeding or fail to have a bowel Stop use and ask a doctor if

> > suq cısımba

- you may have stomach discomfort, faintness
- do not use within 1 hour after taking an antacid do not chew or crush tablet(s) When using this product

Than 2 weeks

- a sudden change in bowel habits that lasts more a stomach pain, nausea or vomiting
 - Ask a doctor before use if you have

Do not use if you cannot swallow without chewing.

methyparaben, polydextrose, polyethyene potose anhydrous, magnesium stearate, aluminum lake, hypromellose, iron oxide black, yellow #10 aluminum lake, FD&C yellow #6 colloidal anhydrous silica, com starch, D&C hydroxide, calcium carbonate, carnauba wax, Inactive ingredients acacia, ammonium

- a see end flap for expiration date and lot number Defineen 15°-30°C (59°-86°F)
- store at 25°C (77°F); excursions permitted BROKEN syoid excessive humidity PACKAGE IS OPENED OR BLISTER IS TORN OR RATUO TI 32U TON OO :TN30IV3 R39MAT = Other information

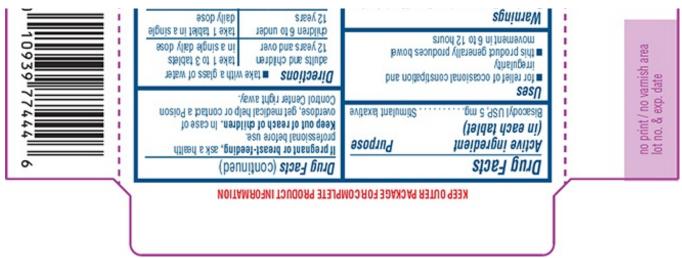
quildren under 6 years | ask a doctor

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

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Rev.



Sunmark 44-327

GENTLE LAXATIVE

bisacodyl tablet, delayed release

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:49348-032

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)
BISACODYL
BISACODYL
BISACODYL
5 mg

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 (UNII: H77VEI93A8)	
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: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

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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			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:49348- 032-05	1 in 1 CARTON	03/25/2002	05/04/2025		
1		25 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:49348- 032-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/25/2002	11/01/2023		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC Monograph Drug	505G(a)(3)	03/25/2002	05/04/2025	

Labeler - Strategic Sourcing Services, LLC (Sunmark) (116956644)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(49348-032) , pack(49348-032)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(49348-032) , pack(49348-032)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(49348-032)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(49348-032)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(49348-032)

Revised: 12/2023 Strategic Sourcing Services, LLC (Sunmark)