BISACODYL- bisacodyl tablet, delayed release
Major Pharmaceuticals

Major 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
- 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

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 0904-6748-17

Compare to the active ingredient
in Dulcolax® Laxative Tablets*

Major®

Bisacodyl USP
5 mg

Stimulant Laxative

Gentle, Dependable
Constipation Relief

Actual Size

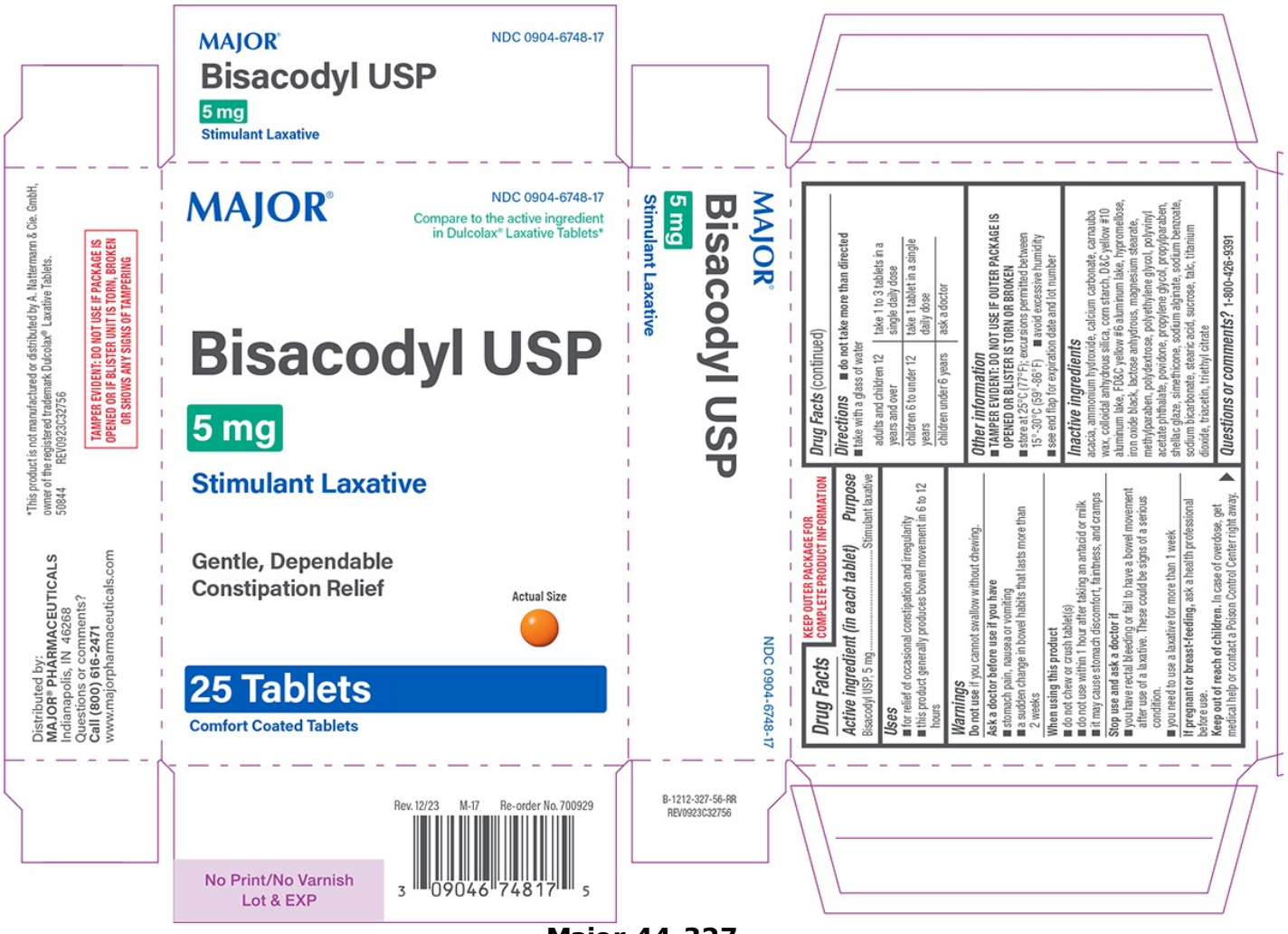
25 TABLETS
Comfort Coated Tablets

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

*This product is not manufactured or distributed by A. Nattermann & Cie. GmbH, owner of the registered trademark Dulcolax® Laxative Tablets.
50844 REV0923C32756

Distributed by:
MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268
Questions or comments?
Call (800) 616-2471
www.majorpharmaceuticals.com

Rev. 12/23 M-17 Re-order No. 700929



Major 44-327

BISACODYL

bisacodyl tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6748
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
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: 3WQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
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
1	NDC:0904-6748-17	1 in 1 CARTON	12/01/2018	
1		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-6748-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2018	
3	NDC:0904-6748-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	12/01/2018	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(0904-6748) , pack(0904-6748)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-6748) , pack(0904-6748)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0904-6748)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0904-6748)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0904-6748)