BISACODYL- bisacodyl tablet, coated
Major Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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
- 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	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

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive humidity
- use by expiration date on package

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?

(800)-616-2471

Principal display panel

NDC 0904-6748-60

Compare to the active ingredient in Dulcolax® Laxative Tablets*

Major®

Bisacodyl USP
5 mg

Stimulant Laxative

Gentle, Dependable
Constipation Relief

Actual Size

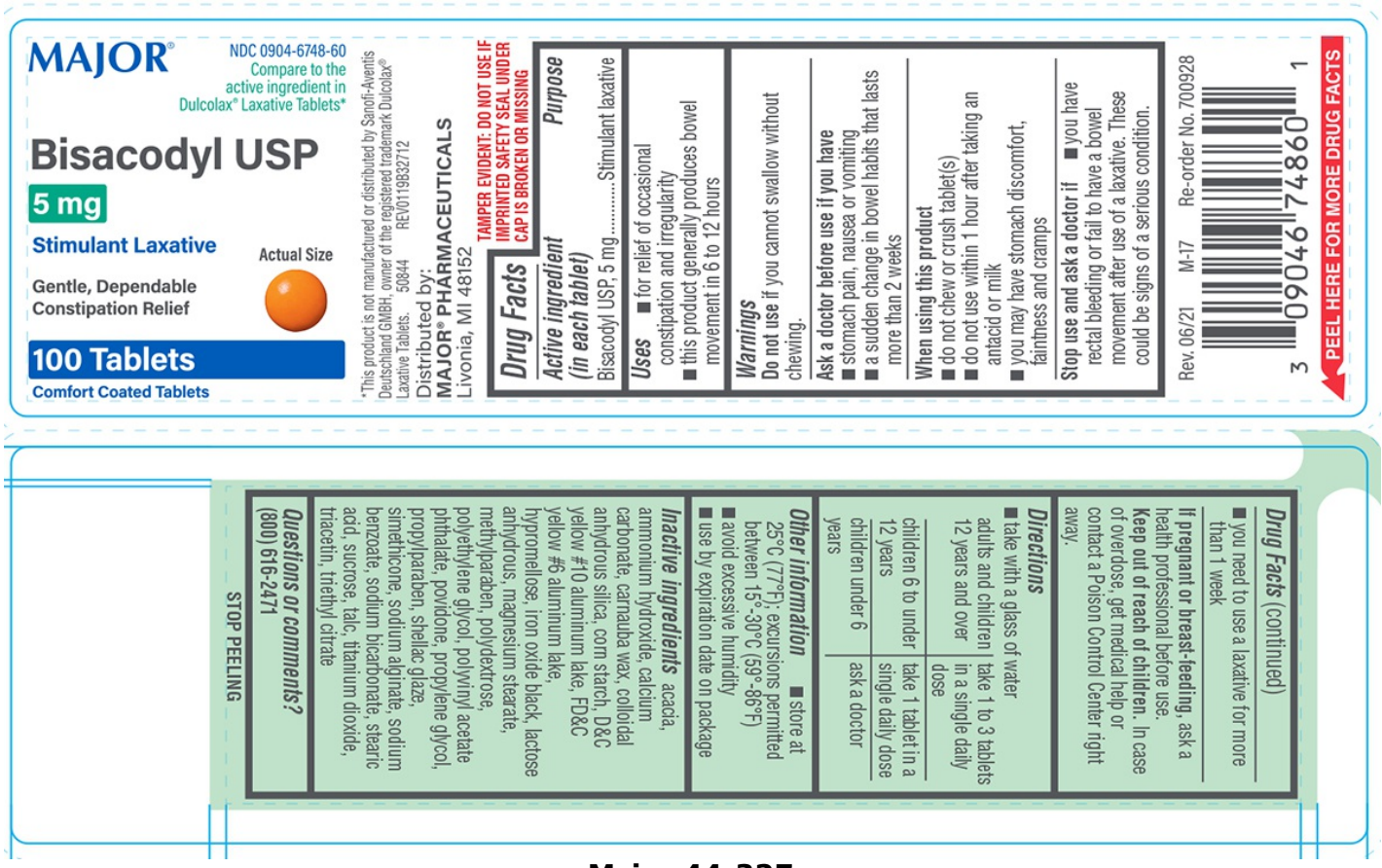
100 TABLETS
Comfort Coated Tablets

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by Sanofi-Aventis Deutschland GMBH, owner of the registered trademark Dulcolax® Laxative Tablets. 50844 REV0119B32712

Distributed by
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152

M-17 Rev. 06/21 Re-order No. 700928



Major 44-327

BISACODYL

bisacodyl tablet, coated

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)	
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: 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)	
AMMONIA (UNII: 5138Q19F1X)	

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 not final	part334	12/01/2018	

Labeler - Major Pharmaceuticals (191427277)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(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.		038154464	pack(0904-6748)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(0904-6748)