

GENTLE LAXATIVE- bisacodyl tablet, sugar coated
L.N.K. International, Inc.

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.

Quality Plus 44-607

Active ingredient
(in each tablet)

Bisacodyl USP 5 mg

Purpose

Stimulant laxative

Uses

- for temporary 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 or cramps

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel moment 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 of age	take 1 tablet in a single daily dose
children under 6 years of age	ask a doctor

Other information

- 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, corn starch, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac, silica, 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

**QUALITY
PLUS**

NDC 50844-607-56

**Compare to the active ingredient
in Dulcolax[®] Pink[™]*

Gentle Laxative
Bisacodyl USP 5 mg
Stimulant Laxative

*Gentle, predictable
overnight relief*

25 Tablets

COMFORT COATED

Actual Size

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

**This product is not manufactured or distributed by
Boehringer Ingelheim Pharmaceuticals, Inc., owner of
the registered trademark Dulcolax[®] Pink[™].
50844 ORG101260756*

Distributed by **LNK INTERNATIONAL, INC.**
60 Arkay Drive, Hauppauge, NY 11788
USA



Gentle Laxative

Bisacodyl USP 5 mg
Stimulant Laxative

NDC 50844-607-56

*Compare to the active ingredient
in Dulcolax® Pink™



Gentle Laxative

Bisacodyl USP 5 mg
Stimulant Laxative

Gentle, predictable
overnight relief



25 Tablets

COMFORT COATED

Actual Size

Gentle Laxative

Bisacodyl USP 5 mg
Stimulant Laxative



B-1603-607-56
ORG101260756



OMIT E

TAMPER EVIDENT: DO NOT USE IF CARTON IS
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Boehringer Ingelheim Pharmaceuticals, Inc., owner of
the registered trademark Dulcolax® Pink™.
50844 ORG101260756
Distributed by LNK INTERNATIONAL, INC.
60 Arkay Drive, Hauppauge, NY 11788
USA

Drug Facts (continued)
propylene glycol, propylparaben, shellac, silica,
simeicone, sodium alginate, sodium benzoate, sodium
bicarbonate, stearic acid, sucrose, talc, titanium dioxide,
tracetin, triethyl citrate
Questions or comments? 1-800-426-9391

A1854R1

Keep out of reach of children. In case of overdose,
professional advice use.
get medical help or contact a Poison Control Center,
right away.
Directions ■ take with a glass of water
adults and children take 1 to 3 tablets
in a single daily dose
children 6 to under 12 years of age take 1 tablet in a single
daily dose
children under 6 years ask a doctor
of age
Other information
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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, corn
starch, D&C red #27 aluminum lake, FD&C blue #2
aluminum lake, FD&C yellow #6 aluminum lake,
aluminum lake, hypromellose, iron oxide black, lactose, magnesium
stearate, methylparaben, polydextrose, polyethylene
glycol, polyvinyl acetate phthalate, povidone,

Uses
■ Bisacodyl USP 5 mg..... Stimulant laxative
■ for temporary relief of occasional constipation and
irregularity
■ this product generally produces bowel movement in
6 to 12 hours
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movement after use of a laxative. These could be
signs of a serious condition.



Quality Plus 44-607

GENTLE LAXATIVE

bisacodyl tablet, sugar coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50844-607
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)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
SHELLAC (UNII: 46N107B71O)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4RIU)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	PINK	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:50844-607-56	1 in 1 CARTON	04/01/2013	
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 NOT FINAL	part334	04/01/2013	

Labeler - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(50844-607)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(50844-607)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(50844-607)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(50844-607)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(50844-607)

Revised: 4/2020

L.N.K. International, Inc.