

**BISACODYL- bisacodyl tablet, coated
REMEDYREPACK 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.

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

DRUG: Bisacodyl

GENERIC: Bisacodyl

DOSAGE: TABLET, COATED

ADMINISTRATION: ORAL

NDC: 70518-1864-0

NDC: 70518-1864-1

COLOR: orange

SHAPE: ROUND

SCORE: No score

SIZE: 6 mm

IMPRINT: 5

PACKAGING: 30 in 1 BLISTER PACK

PACKAGING: 30 in 1 BLISTER PACK

ACTIVE INGREDIENT(S):

- BISACODYL 5mg in 1

INACTIVE INGREDIENT(S):

- POVIDONE, UNSPECIFIED
- TRIACETIN
- TITANIUM DIOXIDE
- TALC
- SUCROSE
- STEARIC ACID
- SODIUM BICARBONATE
- SODIUM BENZOATE
- SODIUM ALGINATE
- WATER
- DIMETHICONE
- SHELLAC
- PROPYLPARABEN
- PROPYLENE GLYCOL
- TRIETHYL CITRATE
- AMMONIA
- POLYETHYLENE GLYCOL, UNSPECIFIED
- POLYDEXTROSE
- METHYLPARABEN
- MAGNESIUM STEARATE
- ANHYDROUS LACTOSE
- FERROSOFERRIC OXIDE
- HYPROMELLOSE, UNSPECIFIED
- FD&C YELLOW NO. 6
- D&C YELLOW NO. 10 ALUMINUM LAKE
- STARCH, CORN
- SILICON DIOXIDE
- CARNAUBA WAX
- CALCIUM CARBONATE
- Polyvinyl Acetate Phthalate
- ACACIA

Bisacodyl

Stimulant Laxative
Enteric Coated

5 mg

Tablet

QTY: 30



NDC #: 70518-1864-00

Expires:

LOT #:

Source NDC: 00904-6748-80

MFG: Major Pharma, Livonia, MI 48152

Keep this and all medication out of the reach of children



Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762

NOT FOR RETAIL SALE

Bisacodyl

Stimulant Laxative
Enteric Coated

5 mg

Tablet

QTY: 30



NDC #: 70518-1864-01

Expires:

LOT #:

Source NDC: 00904-6748-60

MFG: Major Pharma, Livonia, MI 48152

Keep this and all medication out of the reach of children



Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762

NOT FOR RETAIL SALE

BISACODYL

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70518-1864(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
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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)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
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:70518-1864-0	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/13/2019	
2	NDC:70518-1864-1	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	05/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/13/2019	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 3/2022

REMEDYREPACK INC.