# UNIT DOSE BISACODYL- bisacodyl tablet, delayed release Cardinal Health 107, LLC

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Major 44-327

# Active ingredient (in each tablet)

Bisacodyl 5 mg

**Enteric Coated Tablets** 

# Purpose

Stimulant laxative

#### Uses

- relieves occasional constipation and irregularity
- this product generally produces bowel movement in 6 to 12 hours

# Warnings

This Unit Dose package is not child resistant and is Intended for Institutional Use Only. 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.

#### 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

- have rectal bleeding or fail to have a bowel movement after use of a laxative. These
  may be signs of a serious condition.
- you need to use a laxative for more than 1 week

### 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

# 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

Distributed By:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152 USA

Distributed By:

**Cardinal Health** 

Dublin, OH 43017

L5071915-10524

L5071915-20524

# **Principal Display Panel**

BISACODYL USP 5 mg

#### 10 TABLETS



### **BISACODYL USP 5 mg Enteric Coated Tablets**

10 TABLETS

Stimulant laxative

**Drug Facts** 

Active ingredient (in each tablet) Bisacodyl USP, 5 mg

Purpose Stimulant laxative

- for relief of occasional constipation and irregularity - this product generally produces bowel movement in 6 to 12 hours

Directions - take with a glass of water

adults and children 12 take 1 to 3 tablets in a years and over single daily dose children 6 to under 12 take 1 tablet in a single daily dose years children under 6 years ask a doctor

STORAGE: Store at 25° C (77° F); excursions permitted between 15° - 30° C (59° - 86° F)

- avoid excessive humidity

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. 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.

Questions or comments? 1-800-426-9391

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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 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

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

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

### **UNIT DOSE BISACODYL**

bisacodyl tablet, delayed release

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-6897(NDC:0904-6407)
Route of Administration	ORAL		

### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

Inactive Ingredients			
Ingredient Name	Strength		
<b>ACACIA</b> (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: 3WJQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
SHELLAC (UNII: 46N107B710)	
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			

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55154- 6897-0	10 in 1 BAG	03/25/2002		
1	_	1 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 Drug	M007	03/25/2002	

# Labeler - Cardinal Health 107, LLC (118546603)

Revised: 6/2024 Cardinal Health 107, LLC