

BISACODYL ENTERIC COATED- 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.

Bisacodyl Enteric Coated Tablet

Active ingredient(s)

Bisacodyl 5mg

Purpose

Stimulant laxative

Use(s)

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

Warnings

Do not use

Do not use if you cannot swallow without chewing

Ask a doctor before use if

- you have a sudden change in bowel habits that lasts more than 2 weeks
- stomach pain, nausea or vomiting

When using this product

- do not use within 1 hour after taking an antacid or milk
- do not chew or crush tablet(s)
- 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

Pregnancy/Breastfeeding

ask a health professions before use.

Keep out of reach of children

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 degrees C (77 degrees F) excursions permitted between 15 degrees-30 degrees C (59 degrees-86 degrees F)
-use by expiration date on package
-protect from excessive humidity

Storage**Inactive ingredients**

acacia, bees wax, calcium sulfate, carnauba wax, cellulose, corn starch, D&C Yellow No. 10 lake, FD&C Yellow No. 6 lake, gelatin, lactose, magnesium stearate, pharmaceutical glaze, polyvinyl acetate phthalate, silica gel, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide.

Questions

To Report Adverse Drug Event call: (800) 616-2471

Principal Display Panel

Bisacodyl Enteric Coated Tabs, USP 5mg



NDC 0904-7927-61

Unit Dose

BISACODYL
ENTERIC COATED TABLETS
(Delayed Release)

5 mg.

Stimulant Laxative
100 TABLETS

Drug Facts

<i>Active Ingredient (in each tablet)</i>	<i>Purpose</i>
Bisacodyl 5mg	Stimulant laxative

Uses

- relieves 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 over 2 weeks

When using this product

- do not chew or crush tablet
- 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. These may be signs of a serious condition.
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding, ask a doctor before use.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over

take 1 to 3 tablets (usually 2) in a single daily dose

children 6 to under 12 years

take 1 tablet daily

children under 6 years

ask a doctor

Other Information: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature]. Avoid excessive humidity.

Inactive Ingredients acacia, bees wax, calcium sulfate, carnauba wax, cellulose, corn starch, D&C yellow #10 lake, FD&C yellow #6 lake, gelatin, lactose, magnesium stearate, pharmaceutical glaze, polyvinyl acetate phthalate, silica gel, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide.

Questions? To Report Adverse Drug Event Call: (800)616-2471

M-17

Rev. 04/12

PN: 1101

Distributed by
MAJOR® PHARMACEUTICALS
31778 Enterprise Drive
Livonia, MI 48150 USA
Re-Order No. 301566



BISACODYL ENTERIC COATED

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7927
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0 709 Y6 I) (DEACETYLBISACODYL - UNII:R090 78 E41 Y)	BISACODYL	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
AMMONIUM NONOXYNOL-4 SULFATE (UNII: 9HIA70O4J0)
SHELLAC (UNII: 46N107B71O)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STEARIC ACID (UNII: 4ELV7Z65AP)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)

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:0904-7927-17	25 in 1 BLISTER PACK; Type 0: Not a Combination Product	10/24/2008	07/31/2020
2	NDC:0904-7927-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/24/2008	05/31/2021
3	NDC:0904-7927-61	100 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	10/24/2008	02/28/2018
4	NDC:0904-7927-80	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/24/2008	05/31/2021

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/24/2008	05/31/2021

Labeler - Major Pharmaceuticals (191427277)