

BISACODYL ENTERIC COATED- bisacodyl tablet, coated
Aphena Pharma Solutions - Tennessee, LLC

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

Repackaged by Aphena Pharma Solutions - TN.

See **Repackaging Information** for available configurations.



Storage

-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

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

Repackaging Information

Please reference the **Product Characteristics** section listed below for a description of individual tablets or capsules. This drug product has been received by Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

Count	4mg
04	67544-655-04
06	67544-655-06

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20130612AW

PRINCIPAL DISPLAY PANEL - 5mg

NDC 67544-655 - **Bisacodyl 5mg**

NDC # 67544-0655-06

Bisacodyl Enteric Coated

5mg 6 Tablets

Store between 20-25 degrees C (68-77 degrees F).
See USP Controlled Room Temperature.
Dispense in a tight light-resistant container as defined by USP.
Keep this and all drugs out of the reach of children.

Mfg. By: Major Pharmaceuticals
Livonia, MI

Repackaged by Aphena Pharma
Cookeville, TN 38506

Bisacodyl Enteric Coated 5mg 6 Tablets

Bisacodyl Enteric Coated

5mg 6 Tablets

N 67544-0655-06

Batch:
Exp:
Lot:

N 67544-0655-06

BISACODYL ENTERIC COATED

bisacodyl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67544-655(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: 3S Y5LH9 PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

SILICON DIO XIDE (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 DIO XIDE (UNII: 15FIX9V2JP)
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	6 mm
Flavor		Imprint Code	5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67544-655-04	04 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2010	
2	NDC:67544-655-06	06 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	10/24/2008	

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	Repack(67544-655)