

BISACODYL- bisacodyl tablet, delayed release
Aphena Pharma Solutions - Tennessee, LLC

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

Repackaging Information

This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

Count	5 mg
2	71610-700-02
3	71610-700-03
4	71610-700-04
6	71610-700-06
8	71610-700-08
20	71610-700-20

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:

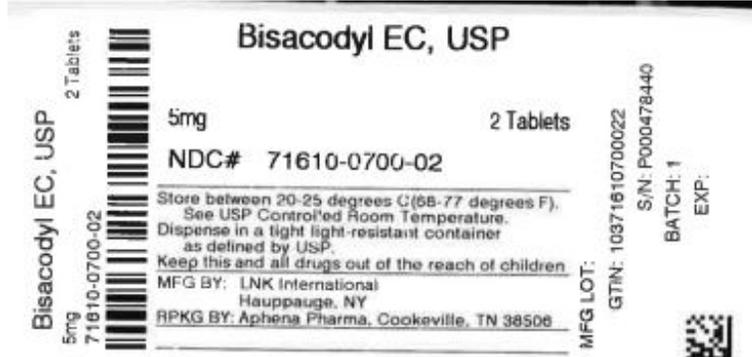


Cookeville, TN 38506

20230406JK

PRINCIPAL DISPLAY PANEL - 5 mg

NDC 71610-700 - Bisacodyl EC, USP 5 mg Tablets - Rx Only



BISACODYL			
bisacodyl tablet, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-700(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
	ACACIA (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 (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: 3WJQ0SDW1A)
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
SHELLAC (UNII: 46N107B710)
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)

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:71610-700-02	2 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2023	
2	NDC:71610-700-03	3 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2023	
3	NDC:71610-700-04	4 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2023	
4	NDC:71610-700-06	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2023	
5	NDC:71610-700-08	8 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2023	
6	NDC:71610-700-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	12/01/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	repack(71610-700)

Revised: 1/2025

Aphenia Pharma Solutions - Tennessee, LLC