STIMULANT LAXATIVE ENTERIC COATED- bisacodyl tablet
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.

441

Active ingredient (in each tablet)

Bisacodyl 5 mg

Purpose

Stimulant Laxative

Uses

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

Warnings

Do not use

• for more than one week unless directed by a doctor

• if you cannot swallow without chewing

• within 1 hour after taking an antacid or milk

Ask a doctor before use if you have

• abdominal pain

• nausea

• vomiting

• a sudden change in bowel habits that lasts longer than 2 weeks

When using this product • abdominal discomfort, faintness, or cramps may occur

Stop use and ask a doctor

• if you have no bowel movement within 12 hours

• if you have rectal bleeding

• these could be signs of a serious condition

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

• do not take more than directed
• swallow whole, do not chew or crush
• take recommended dose in a single daily dose
• take with water
• adults and children 12 years and older: take 1-3 (usually 2) tablets daily
• children 12 and under: ask a doctor

Other information

• store at room temperature
• avoid excessive humidity
• Tamper Evident: Do not use if imprinted seal under cap is missing or broken
• package not child resistant
• for institutional use only

Inactive ingredients

Acacia, Ammonium Hydroxide, Calcium Carbonate, Corn Starch, D and C Yellow NO. 10 Lake, FD and C Yellow NO. 6 Lake, Hypromellose, Iron Oxide Black, Lactose, Magnesium Stearate, Methylparaben, PEG, Polydextrose, Polyvinyl Acetate Phthalate, Propylparaben, Propylene Glycol, Povidone, Shellac, Simethicone, Silica, Sodium Alginate, Sodium Benzoate, Sodium Bicarbonate, Stearic Acid, Sucrose, Talc, Titanium Dioxide, Triacetin, Triethyl Citrate, Wax. May also contain: Calcium Sulfate, Gelatin, Sodium Starch Glycolate.

Repackaging Information

Please reference the ***How Supplied*** section listed above for a description of individual tablets. 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	5 mg
2	71610-453-02
4	71610-453-04
20	71610-453-20

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:

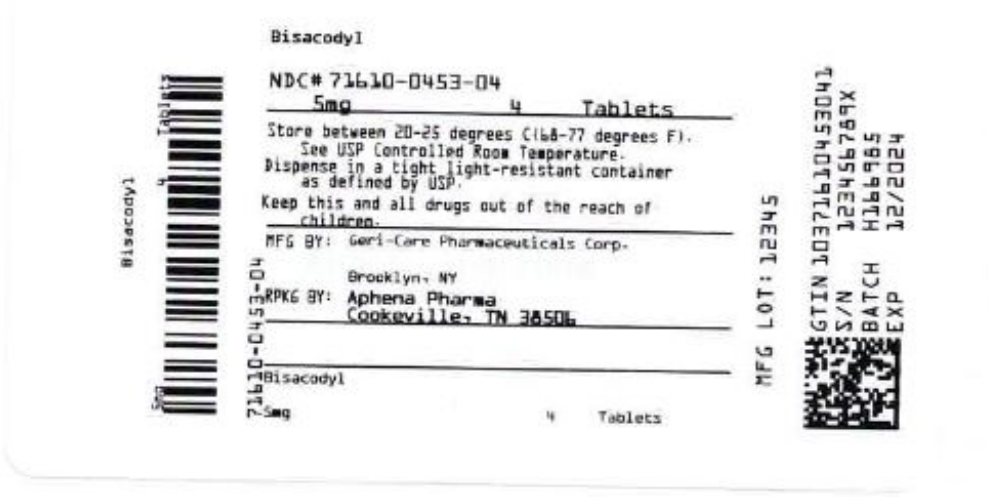
Aphena Pharma Solutions

Cookeville, TN 38506

20200805JH

PRINCIPAL DISPLAY PANEL - 5 mg

NDC 71610-453 - Bisacodyl 5 mg Tablets



STIMULANT LAXATIVE ENTERIC COATED

bisacodyl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71610-453(NDC:57896-441)
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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:71610-453-02	2 in 1 BOTTLE; Type 0: Not a Combination Product	08/28/2020	
2	NDC:71610-453-04	4 in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2020	
3	NDC:71610-453-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2000	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-453)

Revised: 10/2021 Aphena Pharma Solutions - Tennessee, LLC