BISACODYL ENTERIC COATED- bisacodyl tablet, coated
Clinical Solutions Wholesale

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

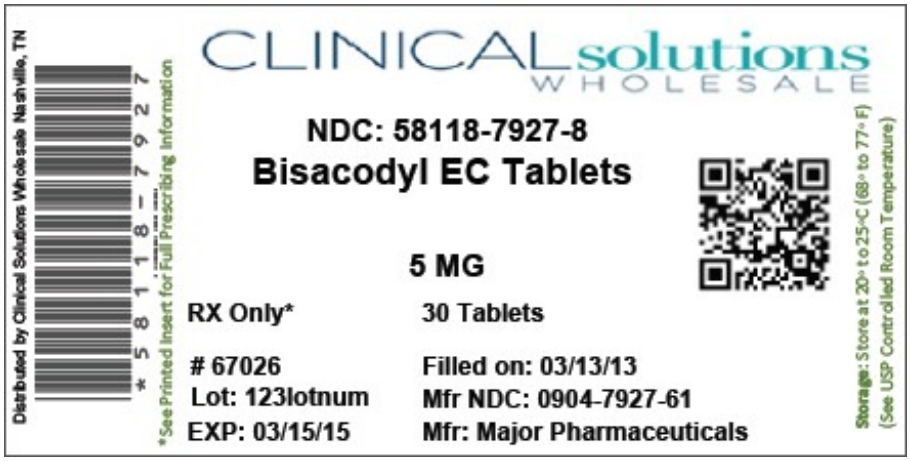
acacia, bees wax, calcium sulfate, carnauba wax, cellulose, corn starch, D&C Yellow No. 10 lake, FD&C Yellow No. 6 lake, gelatin, lactose, magnesium stearate, pharmaceutical glaze, polyvinyl acetate phthalate, silica gel, sodium starch glycolate, stearinc acid, sugar, talc, titanium dioxide.

Questions

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

Principal Display Panel

Bisacodyl Enteric Coated Tabs, USP 5mg



BISACODYL ENTERIC COATED

bisacodyl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58118-7927(NDC:0904-7927)

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y6I) (BISACODYL - UNII:10X0709Y6I)	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 (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (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:58118-7927-3	30 in 1 BOTTLE		
2	NDC:58118-7927-6	60 in 1 BOTTLE		
3	NDC:58118-7927-9	90 in 1 BOTTLE		
4	NDC:58118-7927-8	30 in 1 BLISTER PACK		
5	NDC:58118-7927-0	1 in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part334	10/24/2008	

Labeler - Clinical Solutions Wholesale (078710347)

Registrant - Clinical Solutions Wholesale (078710347)

Establishment

Name	Address	ID/FEI	Business Operations
Clinical Solutions Wholesale		078710347	REPACK(58118-7927) , RELABEL(58118-7927)

Revised: 7/2014 Clinical Solutions Wholesale