ENTERIC COATED STIMULANT LAXATIVE- bisacodyl tablet, delayed release Aidarex Pharmaceuticals 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.

DRUG FACTS

Active ingredient (in each tablet)

Bisacodyl 5 mg

Purpose

Laxative

Uses

- relieves occasional constipation
- generally produces bowel movement in 6-12 hours

Warnings

Do not use

- for longer than one week
- when abdominal pain, nausea or vomiting are present
- in children under 6 years of age
- in persons who cannot swallow without chewing

Ask a doctor before use if you have noticed a sudden change in bowel habits that lasts over two weeks

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

When using this product

- do not take dose within one hour of taking an antacid or milk
- you may experience abdominal discomfort, faintness and cramps

Stop use and ask a doctor if

- vou have rectal bleeding
- you fail to have a bowel movement after use of this product

These may indicate 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 CHEW TABLETS

adults and children 12 years and over: 1-3 tablets once daily

children 6 to 11 years: 1 tablet once daily children under 6 years: ask a doctor

Other information

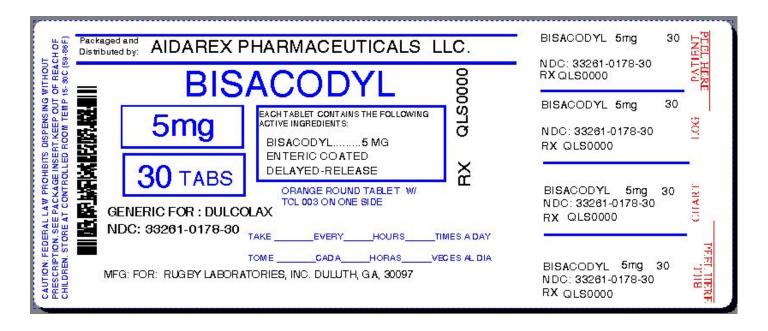
store at 20°-25°C (68°-77°F)

Inactive ingredients acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D-C yellow #10 aluminum lake, FD-C yellow #6 aluminum lake, gelatin, iron oxide, iron oxide black, iron oxide yellow (iron oxide ochre), magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

Questions or comments?

call 1-800-645-2158 9 am - 5 pm ET, Monday - Friday

Repackaged By : Aidarex Pharmaceuticals LLC, Corona, CA 92880



ENTERIC COATED STIMULANT LAXATIVE bisacodyl tablet, delayed release Product Information Product Type HUMAN OTC DRUG Route of Administration HUMAN OTC DRUG ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0 70 9 Y6 I) (BISACODYL - UNII: 10 X0 70 9 Y6 I)	BISACODYL	5 mg

Inactive Ingredients		
Ingredient Name	Strength	
ACACIA (UNII: 5C5403N26O)		
CALCIUM SULFATE ANHYDRO US (UNII: E934B3V59H)		
ANHYDRO US LACTO SE (UNII: 3SY5LH9 PMK)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
STARCH, CORN (UNII: O8232NY3SJ)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERROSOFERRIC OXIDE (UNII: XM0 M87F357)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)		
PO VIDO NES (UNII: FZ989 GH94E)		
SHELLAC (UNII: 46 N10 7B71O)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SUCROSE (UNII: C151H8M554)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics				
Color	ORANGE	Score	no score	
Shape	ROUND	Size	6 mm	
Flavor		Imprint Code	TCL;003	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:33261-178-06	6 in 1 BOTTLE, PLASTIC				
2	NDC:33261-178-30	30 in 1 BOTTLE, PLASTIC				

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	09/22/2011	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 12/2013 Aidarex Pharmaceuticals LLC