

WOMENS GENTLE LAXATIVE- bisacodyl tablet, coated
CVS HEALTH CORP

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.

151R CVS BISACODYL WOMEN'S GENTLE LAXATIVE 69842-089

ACTIVE INGREDIENT

In each tablet: Bisacodyl 5mg

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Acadia, Anhydrous Calcium Sulfate, Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Corn Starch, D&C red #27, FD&C blue#2 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 Phthalates, Povidone, Shellac, Sodium Starch Glycolate, Stearic Acid, Sugar, Talc, Titanium Dioxide

PURPOSE

Stimulant Laxative

Stimulant Laxative

Uses:

relieves occasional constipation and irregularity

this product generally produces a bowel movement in 6 to 12 hours

DOSAGE & ADMINISTRATION

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

Keep out of Reach of Children:

In case of overdose, get medical help or contact a Poison Control Center right away.

Warning: 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 two weeks.

When using this product: Do not chew or crush tablet(s); Do not use within 1 hour after taking an antacid or milk; Do not use this product if you have stomach discomfort, faintness or cramps.



WOMENS GENTLE LAXATIVE

bisacodyl tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69842-089

Route of Administration	ORAL
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
GELATIN (UNII: 2G86QN327L)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	pink	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	TCL
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-089-52	25 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/24/2020	

Labeler - CVS HEALTH CORP (062312574)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(69842-089)

Revised: 8/2020

CVS HEALTHCORP