WOMENS LAXATIVE- bisacodyl tablet, coated RETAIL BUSINESS SERVICES, 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.

Care One Gentle Laxative

Active ingredient (in each tablet)

Bisacodyl USP 5 mg

Purpose

Stimulant laxative

Use

- for temporary relief of occasional constipation and irregularity
- this product generally produces a 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
- it may cause stomach discomfort, faintness and cramps

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using this product. 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 of age and	take 1 to 3 tablets in a single daily
over	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

- each tablet contains: magnesium 5 mg
- store between 20-25°C (68-77°F)

Inactive ingredients

acacia, calcium sulfate anhydrous, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D&C red # 27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, iron oxide, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

Questions or comments?

Call 1-888-333-9792

Principal Display Panel

Compare to active ingredient of Dulcolax® Pink® Laxative*

Women's Gentle Laxative Tablets

Bisacodyl 5 mg

Stimulant laxative

Gentle, Overnight relief

*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor or Dulcolax® Pink® Laxative

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

			GENTLE LAXATIVE FOR WOMEN Bisacodyl USP 5 mg	
(in each tablet) Biscody (USP) 5 ng	Drug Facts (continued) Keep out of reach of children. In case of overdose, get medical key or contact a Pelson Control Cartier right away 1(800)222-1222 Directions = take with a glass of water adutta and children 12 1h 03 tablets in a single daily dose children 16 to under 12 table ta a single daily dose children 16 to under 12 tablet in a single daily dose children 16 to under 12 tablet in a single daily dose children 16 to under 12 tablet in a single daily dose children 16 to under 12 tablet in a single daily dose children 16 to under 17 tablet in a single daily dose children 18 to single daily dose tablet in a single daily dose children under 6 years ask a doctor of age concestex he huridity Inactive ingredients cacia, antydrous caldut allox dosis, con stach das CHe # 27 almitum lake, FASC Yellow Yell daminum lake, FASC Bue yellow, constach wax, yellow reanysitum stach, thron oxide yellow reanysitum stach, thron oxide yellow reanysitum stach, thron oxide yellow realise stach, stach, columis, stach, stach, tron oxide yellow realise stach, stach, schline callutes, stack axid, sugar, tak, thanum dioude Questions or comments? t-88-533-0192	GENTLE LAXATIVE FOR WOMEN Bisacodyi USP5 mg OFENDABLE OFENDABLE OFENDABLE OFENDABLE STIMULANT LAXATIVE KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT IS PRODUCT	<section-header></section-header>	GENTLE LA XATIVE WOMEN Bisacodyl USP 5 mg POR GENTLE OPENNABLE OVENNGHT RELIFF STMULAN ELIFF STMULAN COMMON OF STATE COMMON OF
			DIST RIBUTED BY: FOODHOLD USA, LLC LANDOVER, MD 20785 Product of USA 1877-84-59949 © 2019 Ahold Delhaize Licensing Sarl • Quality guaranteed or your money back.	

WOMENS LAXATIVE bisacodyl tablet, coated					
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (So	urce)	NDC:724	76-654
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingre	edient Name		Basis of St	rength	Strength
BISACODYL (UNII: 10X0709Y6I) (DB	EACETYLBISACODYL - UNII:F	R09078E41Y)	BISACODYL		5 mg
Inactive Incredients					
Inactive Ingredients					
	Ingredient Name			S	Strength
ACACIA (UNII: 5C5403N260)					
CALCIUM SULFATE ANHYDROUS	(UNII: E934B3V59H)				
CARNAUBA WAX (UNII: R12CBM0E	IZ)				
SILICON DIOXIDE (UNII: ETJ7Z6XB	U4)				

STARCH, CORN (UNII: 08232NY3SJ)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B710)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
GELATIN (UNII: 2G86QN327L)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	TCL
Contains			

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:72476-654- 25	25 in 1 CARTON	08/23/2019	
1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing	Information		
Marketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - RETAIL BUSINESS SERVICES, LLC (967989935)