WOMENS GENTLE LAXATIVE- bisacodyl tablet BETTER LIVING BRANDS 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.

151R_Albertsons_21130-555_Bisacodyl USP 5 mg-stimulant laxative

Drug Facts

Active ingredient (in each tablet)

Bisacodyl USP, 5 mg

Purpose

Stimulant laxative

Uses

- for relief of occasional constipation and irregularity
- this product generally produces bowel movement in 6-12 hours

Warnings

Do not use

if you cannot swallow without chewing

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- noticed a sudden change in bowel habits that lasts more than 2 weeks

When using this product

- it may cause stomach discomfort, faintness and cramps
- do not chew or crush tablet(s)
- do not use within 1 hour after taking an antacid or milk

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a 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 (1-800-222-1222).

Directions

take with a glass of water

Other information

- each tablet contains: magnesium 5 mg
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package
- protect from excessive humidity

Inactive ingredients acacia, anhydrous calcium sulfate, 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 (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?

1-877-290-4008



Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-555

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
CALCIUM SULFATE (UNII: WATODDB505)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ 989GH94E)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GELATIN (UNII: 2G86QN327L)	
ACACIA (UNII: 5C5403N26O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B710)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

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:21130- 555-30	2 in 1 CARTON	07/10/2023	
1		15 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/10/2023	
final		3.7237232	

Labeler - BETTER LIVING BRANDS LLC. (009137209)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
TIME CAP LABORATORIES, INC.		037052099	manufacture(21130-555)	

Revised: 8/2023 BETTER LIVING BRANDS LLC.