

CARTERS LITTLE PILLS SODIUM-FREE- bisacodyl tablet, delayed release
Church & Dwight Co., Inc.

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.

Active ingredient (in each tablet)

Bisacodyl USP, 5 mg

Purpose

Stimulant laxative

Uses

- for relief of occasional constipation (irregularity)
- this product generally produces a bowel movement in 6 to 12 hours

Warnings

Do not use

- in children under 6 years of age
- if you can't swallow without chewing
- for a period longer than 1 week, unless directed by a doctor

Ask a doctor before use if you have

- stomach pain, nausea, or vomiting
- a sudden change in bowel habits that persists over 2 weeks

When using this product

- do not use within 1 hour after taking an antacid or milk
- do not chew or crush tablets
- you may have stomach discomfort, faintness and cramps

Stop use and ask a doctor if

- you need to use a laxative for more than 1 week
- you fail to have a bowel movement or have rectal bleeding. These could be signs of a serious condition.

Keep out of reach of children.

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

Follow dosage below or use as directed by a doctor

adults and children 12 years of age and over
daily dose

1 to 3 tablets (usually 2) in a single

children 6 to under 12 years of age

1 tablet in a single daily dose

children under 6 years of age

consult a doctor

Other information

- avoid excessive humidity
- store at temperatures not above 86 degrees F (30 C)

Questions or Comments: 1-800-926-5222 M-F from 9-5 ET

Inactive ingredients

Croscarmellose Sodium, Hydroxypropyl Methylcellulose, Lactose, Magnesium Stearate, Methacrylic Acid Copolymer, Microcrystalline Cellulose, Talc, Triacetin, Triethyl Citrate, Zea mays (Corn) Starch

Principal Display

Overnight Relief Guaranteed

CARTERS

LITTLE

PILLS

Carter's

BISACODYL DELAYED-RELEASED TABLETS

STIMULANT LAXATIVE

Sodium-Free

ENTERIC COATED 25 TABLETS

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-906
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2208 (100 MPAS) (UNII: B1QE5P712K)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	C;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-906-25	1 in 1 CARTON	06/01/2011	11/14/2018
1		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:10237-906-75	3 in 1 CARTON	06/01/2011	11/14/2018
2		25 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/01/2011	

Labeler - Church & Dwight Co., Inc. (001211952)**Establishment**

Name	Address	ID/FEI	Business Operations
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Church & Dwight Canada Corp.		253933600	manufacture(10237-906)
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Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	repack(10237-906)

Revised: 11/2018

Church & Dwight Co., Inc.