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 your 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 a directed by a doctor

adults and children 12 years of age and over 1 to 3 tablets

(usually 2) in a single daily dose

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

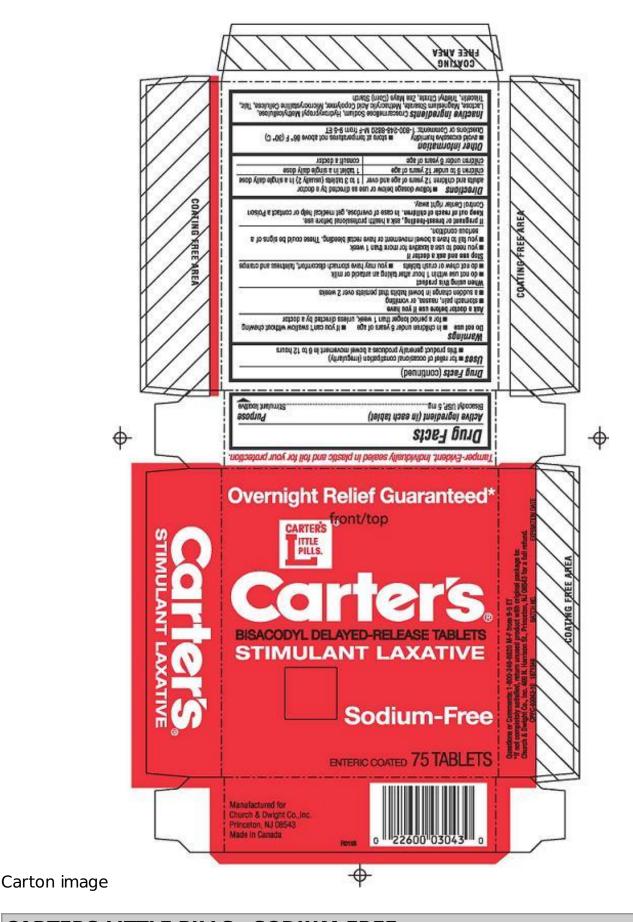
Carter's

BISACODYL DELAYED-RELEASED TABLETS

STIMULANT LAXATIVE

Sodium-Free

ENTERIC COATED 25 TABLETS



CARTERS LITTLE PILLS SODIUM-FREE

bisacodyl tablet, delayed release

| 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 MPA.S) (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 | |
| Church & Dwight Canada Corp. | | 253933600 | manufacture(10237-906) | |

Revised: 1/2023 Church & Dwight Co., Inc.