STIMULANT LAXATIVE ENTERIC COATED- bisacodyl tablet, coated Preferred Plus (Kinray)

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.

Drug Facts

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

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 and over | take 1 to 3 tablets in a single daily 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

• store at controlled room temperature 20°-25°C (68°-77°F)

Inactive ingredients

acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D&C yellow #10 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, and titanium dioxide

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the Active Ingredient in Dulcolax®†

Stimulant LAXATIVE

Bisacodyl, USP, 5 mg per tablet

For dependable relief of occasional constipation

Enteric Coated Tablets

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by: Kinray, Inc.

152-35 Tenth Avenue

Whitestone, NY 11357

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

Package Label



ingelheim Pharmaceuticals, Inc., distributor of Dulcolax® Laxatiw This product is not manufactured or distributed by Boehringer

glycolate, stearic acid, sugar, talc, titanium dioxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch gelatin, iron oxide, iron oxide black, iron oxide estions or comments?

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Drug Facts (continued)

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silicon dioxide, corn starch, D&C yellow #10 Inactive ingredients acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal

store between 20°-25°C (68°-77°F)

ther information

aluminum lake, FD&C yellow #6 aluminum lake

Preffered Plus Stimulant Laxative Tablets

STIMULANT LAXATIVE ENTERIC COATED

bisacodyl tablet, coated

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61715-038 |
| 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 |
| ACACIA (UNII: 5C5403N26O) | |
| CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H) | |

| ANHYDRO US LACTO SE (UNII: 3SY5LH9 PMK) | |
|--|--|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| GELATIN (UNII: 2G86QN327L) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | |
| SHELLAC (UNII: 46 N10 7B710) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | |
| Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3) | |
| PO VIDO NE (UNII: FZ989 GH9 4E) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357) | |
| FERRIC OXIDE YELLOW (UNII: EX438 O2MRT) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| SUCROSE (UNII: C151H8M554) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| | |

| Product Characteristics | | | |
|-------------------------|--------|--------------|----------|
| Color | ORANGE | Score | no score |
| Shape | ROUND | Size | 6mm |
| Flavor | | Imprint Code | TCL003 |
| Contains | | | |

| l | Packaging | | | |
|---|------------------------|---|-------------------------|-----------------------|
| | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 NDC:61715-038- 51 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/13/2010 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH NOT FINAL | part334 | 07/13/2010 | |
| | | | |

Labeler - Preferred Plus (Kinray) (012574513)

Revised: 11/2019 Preferred Plus (Kinray)