BISACODY ENTERIC COATED- bisacodyl tablet, coated MEIJER, 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.

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)
- 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 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 between 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, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

Questions or comments?

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

Principal Display Panel

Compare to the active ingredient in Dulcolax® Laxative

LAXATIVE

Bisacodyl | 5 mg

Stimulant laxative

Gentle, Predictable, Overnight Relief

ENTERIC COATED

Tablets

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.

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

DIST. BY MEIJER DISTRIBUTION, INC. GRAND RAPID, MI 49544 www.meijer.com

Product Label

meijer

NDC 41250-191-25

*Compare to the active ingredient in Dulcolax® Laxative

laxative

Bisacodyl | 5 mg Stimulant laxative

Gentle, Predictable, Overnight Relief

ENTERIC COATED

25 Tablets



UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

FAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER

Lot No.: Exp. Date:

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

DIST. BY MEIJER DISTRIBUTION, INC GRAND RAPIDS, MI 49544 www.meijer.com

PLD-F23K FC005694 OUR QUALITY GUARANTEE The Tuein Family

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Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Inactive ingredients acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal silicon dioxide, com atarch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, FD&C yellow #6 aluminum yellow, magnesium atearate, microcrystalline yelluose, polyethylene glycol, polyvinyl acetate cellulose, povidone, shellac, sodium starch glycolate, stearic acid, sugar, falc, titanium dioxide

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 - Stop use and ask a doctor if

ramps

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

LUSIN Z WEEKS

a sudden change in bowel habits that lasts more

-6-

| Ask a doctor before use if you stomach nain nausea or womi | children under 6 years of | sak a doctor | |
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| short St of 8 ni finemevom | adults and children 12 years of age and over | take 1 to 3 tablets in a single daily dose | |
| USE Tor temporary relief of occasion irregularity This product generally produce | bri Directions | ■ take with a glass of water | |
| Active ingredient (in each tablet) Bisacodyl USP 3 mg | professional before use. Keep out of reach of childr tive overdose, get medical help o | 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. | |
| Drug Facts | Drug Facts (continue | (p | |

MEIJER Laxative

BISACODY ENTERIC COATED

bisacodyl tablet, coated

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41250-191 |
| 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) | | | |
| ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) | | | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | | |
| 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, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | |
| SHELLAC (UNII: 46N107B710) | | | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | |
| TALC (UNII: 7SEV7J4R1U) | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | |

| Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3) | |
|--|--|
| SUCROSE (UNII: C151H8M554) | |
| POVIDONE (UNII: FZ989GH94E) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX43802MRT) | |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| ALUMINUM OXIDE (UNII: LMI2606933) | |

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

| F | Packaging | | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|--|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:41250-191- 25 | 25 in 1 CARTON | 05/31/2016 | 05/31/2025 | | |
| 1 | | 1 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 | 05/31/2016 | 05/31/2025 |
| | | | |

Labeler - MEIJER, INC. (006959555)

Revised: 11/2022 MEIJER, INC.