

**EXTRA GENTLE LAXATIVE- bisacodyl tablet, delayed release
DOLGENCORP 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.

14R Dollar General 55910 954 Bisacodyl Delayed-Release USP,5mg ct25

DRUG FACTS

**Active ingredient
(in each tablet)**

Bisacodyl USP 5 mg

Purpose

Stimulant laxative

Uses

- for temporary relief of occasional constipation and irregularity
- this product generally produces 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
- you may have stomach discomfort, faintness or cramps

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. 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

Other information

- **each tablet contains:** magnesium 5 mg
- store at 25 °C (77 °F) excursions permitted between 15 °C-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 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, titanium dioxide

Questions? Call 1-888-309-9030

Drug Facts (continued)

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

Drug Facts

Active ingredient (in each tablet) Bisacodyl USP 5 mg, Stimulant laxative

Purpose Stimulant laxative

Uses for temporary relief of occasional constipation and irregularity

Warnings Do not use if you cannot swallow without chewing. Ask a doctor before use if you have stomach pain, nausea or vomiting. When using this product do not use within 1 hour after taking an antacid or milk. You may have stomach discomfort, faintness or cramps.

Other information Each tablet contains: magnesium 5 mg. Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F). Protect from excessive humidity.

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.

Drug Facts (continued) Stop use and ask a doctor if you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition. 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.

Warnings Do not use if you cannot swallow without chewing. Ask a doctor before use if you have stomach pain, nausea or vomiting. When using this product do not use within 1 hour after taking an antacid or milk. You may have stomach discomfort, faintness or cramps.

Drug Facts (continued)

Other information Each tablet contains: magnesium 5 mg. Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F). Protect from excessive humidity.

Drug Facts

Active ingredient (in each tablet) Bisacodyl USP 5 mg, Stimulant laxative

Purpose Stimulant laxative

Uses for temporary relief of occasional constipation and irregularity

Warnings Do not use if you cannot swallow without chewing. Ask a doctor before use if you have stomach pain, nausea or vomiting. When using this product do not use within 1 hour after taking an antacid or milk. You may have stomach discomfort, faintness or cramps.

Drug Facts (continued)

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

Drug Facts

Active ingredient (in each tablet) Bisacodyl USP 5 mg, Stimulant laxative

Purpose Stimulant laxative

Uses for temporary relief of occasional constipation and irregularity

Warnings Do not use if you cannot swallow without chewing. Ask a doctor before use if you have stomach pain, nausea or vomiting. When using this product do not use within 1 hour after taking an antacid or milk. You may have stomach discomfort, faintness or cramps.

Laxative Tablets
Bisacodyl Delayed-Release USP, 5mg
Stimulant laxative

DG™ health

Compare to the active ingredient of Dulcolax® Laxative*

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Questions? Call 1-888-309-9030

DISTRIBUTED BY
OLD EAST MAIN CO.
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072

A0201

55910 95452 4

3

*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., owner of the registered trademark Dulcolax®.

14R 0321

EXP. DATE:

LOT #:

TAMPER EVIDENT: EACH TABLET IS SAFETY SEALED.
DO NOT USE IF BILSTER OR FOIL IS BROKEN OR MISSING



EXTRA GENTLE LAXATIVE

bisacodyl tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-954
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 ANHYDROUS (UNII: E934B3V59H)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
GELATIN (UNII: 2G86QN327L)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SHELLAC (UNII: 46N107B71O)	

ACACIA (UNII: 5C5403N26O)
CARNAUBA WAX (UNII: R12CBM0EIZ)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
MAGNESIUM STEARATE (UNII: 70097M6I3O)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)
POVIDONE (UNII: FZ989GH94E)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STEARIC ACID (UNII: 4ELV7Z65AP)
INVERT SUGAR (UNII: ED959S6ACY)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	TCL003
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-954-52	1 in 1 CARTON	07/24/2021	
1		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	07/24/2021	

Labeler - DOLGENCORP INC (068331990)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(55910-954)