

STIMULANT LAXATIVE- bisacodyl tablet, delayed release
TIME CAP LABORATORIES, 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 - BISACODAYL-TCL

In each tablet: Bisacodyl 5mg

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 Phthalates, Povidone, Shellac, Sodium Starch Glycolate, Stearic Acid, Sugar, Talc, Titanium Dioxide

Stimulant Laxative

Keep out of Reach of Children: In case of overdose, get medical help or contact a Poison Control Center right away.

Uses:

- relieves occasional constipation and irregularity
- this product generally produces a bowel movement in 6 to 12 hours

Warning: 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 two weeks.

When using this product: Do not chew or crush tablet(s); Do not use within 1 hour after taking an antacid or milk; Do not use this product if you have stomach discomfort, faintness or cramps.

- adults and children 12 years and over: take 1 to 3 tablets in a single daily dose
- children 6 to under 12 years: take 1 tablet in a single daily dose
- children under 6 years: ask a doctor

25 COUNT BLISTER

A1854

REMAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each tablet)
Bisacodyl 5 mg

Purpose
Stimulant laxative

Uses
relieves 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, flatness or cramps

Drug Facts (continued)
Stop use and ask a doctor if:
no bowel movement 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.

Directions
Take with a glass of water
adults and children 12 years and over take 1 tablet in a single daily dose
children 6 to under 12 years of age take 1 tablet in a single daily dose
children under 6 ask a doctor

Other Information
Keep this and all other medications out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).
Use by expiration date on package
protected from excessive humidity

Drug Facts (continued)
Inactive ingredients acacia, anhydrous calcium sulfate, anhydrous lactose, carmelum 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, stibelic, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

for temporary relief of occasional constipation

Mild, Predictable Overnight Relief

STIMULANT LAXATIVE TABLETS

(bisacodyl delayed-release USP, 5mg)

Bisacodyl

25 ENTERIC-COATED TABLETS

NDC 49483-003-52
Compare to the active ingredient in Dulcolax**



(bisacodyl delayed-release USP, 5mg)

Bisacodyl



LOT #: EXP. DATE:

No Print Lot no. & Exp. Area

This product is not manufactured or distributed by Boehmer Ingelheim Pharmaceuticals, Inc. owner of the registered trademark Dulcolax®, 149 1012 Farmingdale, NY 11735
Manufactured by Time-Cap Labs, Inc. 7 Michael Avenue Farmingdale, NY 11735
TAMPER EVIDENT: EACH TABLET IS SAFETY SEALED. DO NOT USE IF BLISTER OR FOIL IS BROKEN OR MISSING

NDC 49683-003-01
Time-Cap Labs, Inc.
 Compare to the active ingredient in Dulcolax®

Bisacodyl

(bisacodyl delayed-release USP, Simg)
 STIMULANT LAXATIVE TABLETS

Mild, Predictable Overnight Relief
 for temporary relief of occasional constipation

100 TABLETS

*The presence of our delayed-release technology helps to minimize side effects associated with the active ingredient. For more information, visit our website at www.timecap.com.

© 2011 Time-Cap Labs, Inc.
 Manufactured by Time-Cap Labs, Inc.
 1000 CT 14R



Drug Facts
 Active ingredient (in each tablet): Pivone
 Bisacodyl eq. Standard score

Warnings
 Do not use if you are pregnant or breastfeeding.
 Do not use if you are taking other laxatives.
 Do not use if you are taking other medications that may interact with this product.

Directions
 Take 1 tablet with water at bedtime or once daily.
 If you are pregnant or breastfeeding, consult your doctor before using this product.

Other Information
 Each tablet contains 5 mg of bisacodyl.
 Contains 100 tablets.

Keep out of reach of children.
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions • Use with a glass of water.
 Take 1 tablet with water at bedtime or once daily.
 If you are pregnant or breastfeeding, consult your doctor before using this product.

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1000 CT 14R

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
ANHYDROUS LACTOSE (UNII: 3S5YLH9PMK)	
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)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
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:49483-003-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/07/2018	
2	NDC:49483-003-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/07/2018	
3	NDC:49483-003-52	25 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/07/2018	
4	NDC:49483-003-	100000 in 1 CARTON; Type 0: Not a Combination Product	12/07/2018	

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100000 in CARTON, Type 0, Not a Combination Product

12/01/2010

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/01/2014	

Labeler - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(49483-003)

Revised: 9/2019

TIME CAP LABORATORIES, INC.