

**GENTLE LAXATIVE- bisacodyl tablet**  
**WinCo Foods LLC**

*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.*

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**14R Winco Foods 67091 385 Bisacodyl USP 5mg 25 count**

**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, 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

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adults and children 12 years and over  
children 6 to under 12 years of age  
children under 6 years of age

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take 1 to 3 tablets in a single daily dose  
take 1 tablet in a single daily dose  
ask a doctor

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## Other Information

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

Comments & Questions? 800-824-1706



## GENTLE LAXATIVE

bisacodyl tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67091-385
<b>Route of Administration</b>	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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GELATIN (UNII: 2G86QN327L)	
SUCROSE (UNII: C151H8M554)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SHELLAC (UNII: 46N107B71O)	
ACACIA (UNII: 5C5403N26O)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	

## 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:67091-385-25	1 in 1 CARTON	01/12/2022	
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	01/12/2022	

**Labeler** - WinCo Foods LLC (056098817)

**Registrant** - TIME CAP LABORATORIES, INC. (037052099)

### Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(67091-385)

Revised: 1/2022

WinCo Foods LLC