

**BISACODYL- bisacodyl tablet, coated**  
**KROGER COMPANY**

*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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**KROGER 14R BISACODYL 5 MG TABLETS 41226-003**

Active ingredient (in each tablet)

Bisacodyl 5 mg

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

Uses:

relieves occasional constipation and irregularity

this product generally produces a bowel movement in 6 to 12 hours

**DOSAGE & ADMINISTRATION**

- 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

**Warnings**

- 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.

**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.



## BISACODYL

bisacodyl tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41226-003
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0 70 9 Y6 I) (DEACETYLBISACODYL - UNII:R0 90 78 E41 Y)	BISACODYL	5 mg

### Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SUCROSE (UNII: C151H8M554)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STARCH, CORN (UNII: O8232NY3SJ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
ACACIA (UNII: 5C5403N26O)	
TALC (UNII: 7SEV7J4R1U)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
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:41226-003-52	25 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	06/01/2020	

**Labeler** - KROGER COMPANY (006999528)

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

**Establishment**

Name	Address	ID/FEI	Business Operations
TIME CAP LABS		037052099	manufacture(41226-003)

Revised: 6/2020

KROGER COMPANY