

**ENTERIC COATED STIMULANT LAXATIVE- bisacodyl tablet, delayed release**  
**RUGBY 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 RUGBY -BISACODYL 5 MG TABLETS (ORANGE)0536-3381**

**ACTIVE INGREDIENT**

In each tablet: Bisacodyl 5mg

Acadia, 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

**PURPOSE**

Stimulant Laxative

**INDICATIONS & USAGE**

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

**KEEP OUT OF REACH OF CHILDREN**

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

**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 ...

**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.



**ENTERIC COATED STIMULANT LAXATIVE**

bisacodyl tablet, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-3381
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SHELLAC (UNII: 46N107B71O)	
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	

**Product Characteristics**

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL;003
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-3381-01	100 in 1 BOX; Type 0: Not a Combination Product	09/22/2012	

2	NDC:0536-3381-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/22/2012	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part334	09/22/2012		

**Labeler** - RUGBY LABORATORIES INC (079246066)

**Registrant** - TIME CAP LABS, INC (037052099)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
TIME CAP LABORATORIES, INC.		037052099	manufacture(0536-3381)

Revised: 7/2020

RUGBY LABORATORIES INC