BISACODYL- bisacodyl tablet, delayed release
SPIRIT PHARMACEUTICALS 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.

VALUMEDS LAXATIVE

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)
- it may cause stomach discomfort, faintness and cramps
- do not use within 1 hour after taking an antacid or milk

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using this product. 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 1(800)222-1222

Directions

take with a glass of water

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

Other information

- **each tablet contains:** magnesium 5 mg
- store at 20-25°C (68-77°F)
- 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 or comments?

1-888-333-9792

Distributed By

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL - 5 mg tablets bottle

VALUMEDS

Compare to the

active ingredient

in **DULCOLAX®***

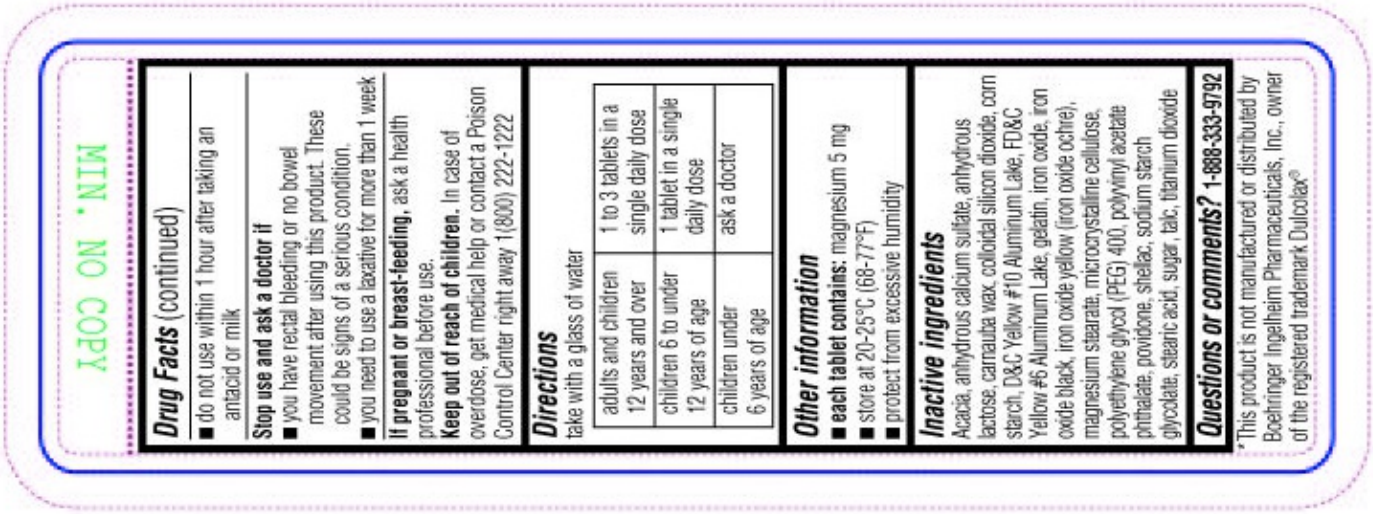
Laxative

BISACODYL USP 5 mg

Gentle

Overnight Relief

100 TABLETS



BISACODYL

bisacodyl tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0312
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**
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	TCL003
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0312-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/19/2017	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
TIME-CAP LABS, INC.		037052099	manufacture(68210-0312)

Revised: 12/2019 SPIRIT PHARMACEUTICALS LLC