BISACODYL - bisacodyl tablet, delayed release
Sunrise Pharmaceutical 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.

Bisacodyl USP 5 mg Laxative

OTC - ACTIVE INGREDIENT

Bisacodyl USP 5mg.

OTC - PURPOSE

Stimulant laxative.

INDICATIONS AND USAGE

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.

OTC - ASK DOCTOR

If you have

Stomach pain, nausea or vomiting

A sudden change in bowel habits that lasts for more than 2 weeks.

OTC - WHEN USING

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.

OTC - STOP USE

And ask a doctor if:

You have rectal bleeding or no bowel movement after using this product. These could be signs of serious condition.

You need to use laxative for more than 1 week

OTC - PREGNANCY OR BREAST FEEDING

Ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN

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

DOSAGE AND ADMINISTRATION

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	1 tablet in a single daily dose
Children under 6 years	Ask a doctor

OTHER INFORMATION

Store at 20(-25(C(68(-77(F). Protect from excessive humidity.

INACTIVE INGREDIENT

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, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Drug Facts (continued)

■ 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.

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	1 tablet in a single daily dose
children under 6 years	ask a doctor

Other information

■ 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, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide.

NDC 11534-156-01

*Compare to active ingredient in Dulcolax®

Bisacodyl USP 5mg LAXATIVE

Relieves Occasional constipation and irregularity

Delayed-Release Tablets Enteric Coated

100 Tablets

Sunrise Pharmaceutical, Inc. Rahway, NJ

Do not use if imprinted seal under cap is missing or damaged

Drug Facts

Active ingredient (in each tablet) — **Purpose**

Bisacodyl USP 5 mg..... 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

Drug Facts (continued on back of label)

Distributed by: Sunrise Pharmaceutical, Inc.
Rahway, NJ 07065
www.sunrisepharma.com

*Sunrise Pharmaceutical, Inc. is not affiliated with the owner of the trademark Dulcolax®.

3 11534 15601 0

LOT #:

EXP. DATE

No Varnish

PEEL HERE

BISACODYL

bisacodyl tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11534-156
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISACODYL (UNII: 10X0709Y6I) (BISACODYL - UNII:10X0709Y6I)	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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
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)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	

Product Characteristics			
Color	ORANGE	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	TCL;003
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:11534-156-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/08/2005	

Labeler - Sunrise Pharmaceutical Inc (168522378)

Revised: 7/2013 Sunrise Pharmaceutical Inc