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

ACTIVE INGREDIENT

Bisacodyl USP 5mg.

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.

ASK DOCTOR BEFORE USE IF YOU HAVE

Stomach pain, nausea or vomiting

A sudden change in bowel habits that lasts for 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 serious condition.

You need to use laxative for more than 1 week

IF PREGNANT OR BREAST FEEDING

Ask a health professional before use.

DOSAGE AND ADMINISTRATION

Dosage and Administration text

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

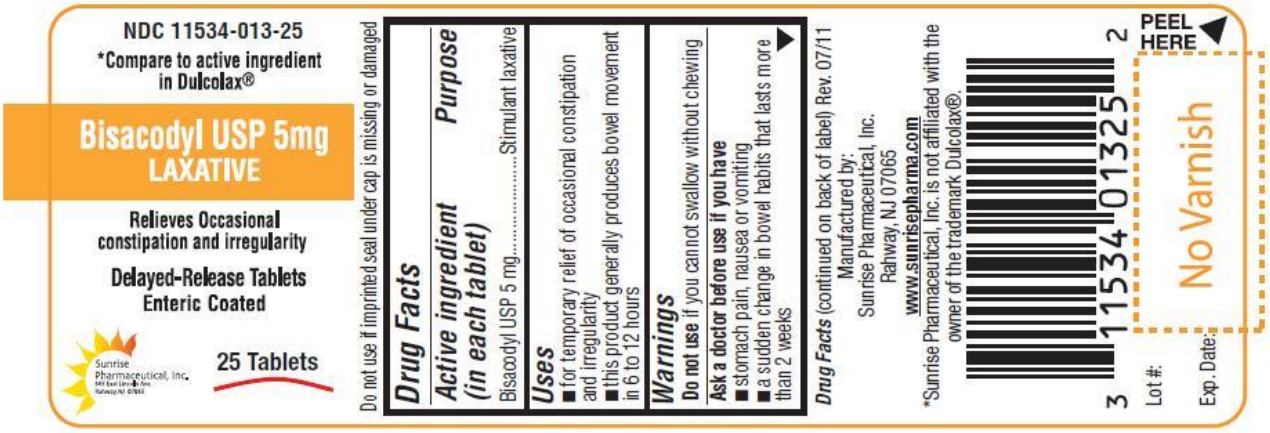
OTHER INFORMATION

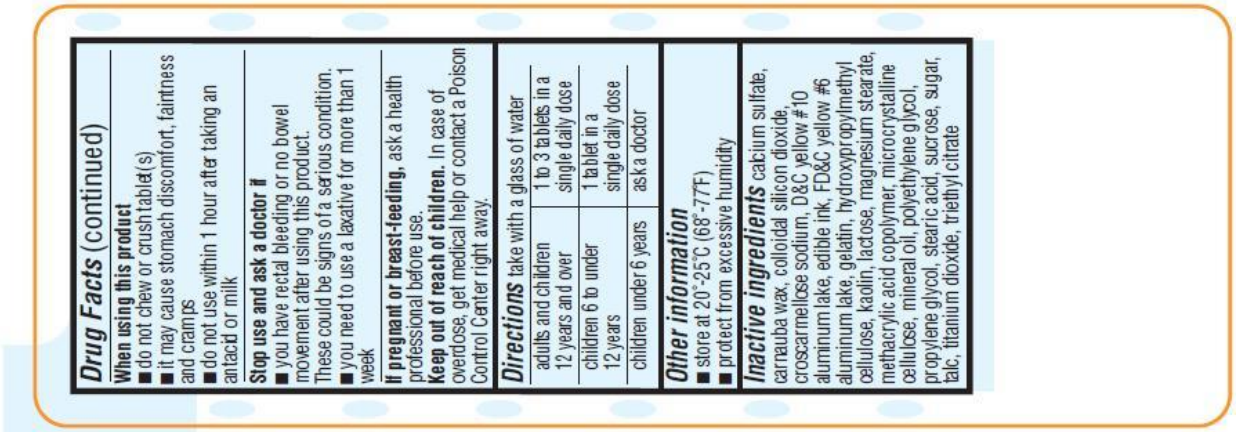
Store at 20°-25°C(68°-77°F)

INACTIVE INGREDIENT

Calcium sulfate, carnuba wax, colloidal silicon dioxide, croscarmellose sodium, D & C yellow # 10, edible ink, FD & C yellow #6, gelatin, hydroxypropylymethyl cellulose, kaolin, lactose, magnesium stearate, methacrylic acid copolymer, microcrystalline celloluse, mineral oil, polyethylene glycol, propylene glycol, stearic acid, sucrose, sugar, talc, titanium dioxide, triethyl citrate.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





BISACODYL

bisacodyl tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11534-013
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**
CALCIUM SULFATE (UNII: WAT0DDB505)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
KAOLIN (UNII: 24H4NWX5CO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	ORANGE	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	S1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11534-013-25	25 in 1 BOTTLE		
2	NDC:11534-013-01	100 in 1 BOTTLE		
3	NDC:11534-013-03	1000 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: 8/2011 Sunrise Pharmaceutical Inc