

BISACODYL STIMULANT LAXATIVE- bisacodyl tablet, delayed release
Physicians Total Care, 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.

DRUG FACTS

Active ingredient (in each tablet)

Bisacodyl 5 mg

Purpose

Laxative

Uses

- relieves occasional constipation
- generally produces bowel movement in 6-12 hours

Warnings

Do not use

- for longer than one week
- when abdominal pain, nausea or vomiting are present
- in children under 6 years of age
- in persons who cannot swallow without chewing

Ask a doctor before use if you have noticed a sudden change in bowel habits that lasts over two weeks

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

When using this product

- do not take dose within one hour of taking an antacid or milk
- you may experience abdominal discomfort, faintness and cramps

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use of this product

These may indicate a serious condition.

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

DO NOT CHEW TABLETS

adults and children 12 years and over: 1-3 tablets once daily

children 6 to 11 years: 1 tablet once daily

children under 6 years: ask a doctor

Other information

store at 20°-25°C (68°-77°F)

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?

call 1-800-645-2158 9 am - 5 pm ET, Monday - Friday



Bisacodyl

Delayed-Release Tablets USP, 5 mg

Enteric Coated Stimulate Laxative

NDC 54868-2497-0

100 tablets

Distributed by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

BISACODYL STIMULANT LAXATIVE			
bisacodyl tablet, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-2497(NDC:0536-3381)
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)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
MAGNESIUM STEARATE (UNII: 70097M6I30)
CELLULOSE, MICROCRYSTALLINE (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	TCL;003
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-2497-0	100 in 1 BOX		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/22/2011	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-2497)

