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

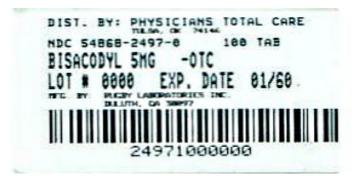
Other information

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								
Ingr	Basis of Strength	Strength						
BISACODYL (UNII: 10X0709Y6I) (BISACODYL - UNII:10X0709Y6I)			BISACODYL	5 mg				
Inactive Ingredients								
Ingredient Name								
ACACIA (UNII: 5C5403N26O)								

CALCIUM SULFATE ANHY	DROUS (UNII: E934B3V59H))							
ANHYDROUS LACTOSE (U	NII: 3SY5LH9PMK)								
CARNAUBA WAX (UNII: R12	CBM0EIZ)								
SILICON DIO XIDE (UNII: ET	ГJ7Z6XBU4)								
STARCH, CORN (UNII: 0823	32NY3SJ)								
D&C YELLOW NO. 10 (UNI	II: 35SW5USQ3G)								
FD&C YELLOW NO.6 (UN	II: H77VEI93A8)								
GELATIN (UNII: 2G86QN32	GELATIN (UNII: 2G86QN327L)								
FERRIC OXIDE RED (UNII: 1K09F3G675)									
FERROSOFERRIC OXIDE (UNII: XM0 M87F357)								
FERRIC OXIDE YELLOW	UNII: EX438O2MRT)								
MAGNESIUM STEARATE (U	JNII: 70097M6I30)								
CELLULOSE, MICROCRYS	TALLINE (UNII: OP1R32D61	1U)							
POLYETHYLENE GLYCOL	400 (UNII: B697894SGQ)								
POLYVINYL ACETATE PH	POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)								
POVIDONE (UNII: FZ989GH	194E)								
SHELLAC (UNII: 46N107B710)									
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)									
STEARIC ACID (UNII: 4ELV)	STEARIC ACID (UNII: 4ELV7Z65AP)								
SUCROSE (UNII: C151H8M554)									
TALC (UNII: 7SEV7J4R1U)									
TITANIUM DIO XIDE (UNII:	15FIX9V2JP)								
Product Characteristi	ics								
Color	orange	nge Score no score			score				
Shape	ROUND	Size 6mm		ım					
Flavor		Imprint Code TCL;0		L;003					
Contains									
Packaging									
# Item Code	Package Descriptio	n	Marketing	g Start Date	Ma	rketing End Date			
1 NDC:54868-2497-0	100 in 1 BOX				8				
Marketing Information									
Marketing Category	Application Number or M	Monogra	aph Citation	Marketing Star	t Date	Marketing End Date			
OTC monograph not final p	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)					