Y LAX DR- bisacodyl tablet, sugar coated
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.

Y LAX TABLETS DR, 5 mg-SUGAR COATED: YELLOW

Drug Facts

Active ingredients (in each tablet)

Bisacodyl 5 mg

Purpose

Stimulant laxative

Uses

- for relief of occasional constipation(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
- vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks

When using this product

- do not chew or crush tablets
- do not take this product within 1 hour after taking an antacid or milk
- it may cause stomach discomfort,faintness, and cramps

Stop use and ask doctor if

- you need to use more than 1 week
- rectal bleeding or failure to have a bowel movement occur after use of a laxative.These may be signs of a serious condition

If pregana 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.

Direction

take with a glass of water

- Do not take more than three tablets daily

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

Other information

- store between 20° to 25°C (68° to 77° F)
- protection from excessive humidity

Inactive ingredients

lactose,cornstarch,povidone (K-30),sodium startch glycolate,talc,magnesium stearate,methacrylic acid copolymer,polethylene glaycol,sodium hydroxide pellets, sucrose,acacia,gelatin,methylparaben, propylparaben, calcium sulphate dihydrate,titanium dioxide,D&C yellow #6 lake, FD & C yellow #10; pharmaceuticals glaze

PRINCIPAL DISPLAY PANEL - 5 mg Shipping Label

Y LAX TABLETS DR, 5 mg-SUGAR COATED: YELLOW

Each Delayed Release Tablet Contains

(Bisacodyl 5 mg Tablets,USP)

LOT NO :
DRUM NO :
MFG. DATE :

QUANTITY : 50000
NDC NO : 68210-0001-5
EXP. DATE :

WARNING :
KEEP OUT OF THE REACH OF CHILDREN

STORE CONTROLLED ROOM TEMPRATURE OF 59° – 86°F (15° – 30°C)
PROTECT FROM LIGHT, MOISTURE AND FREEZING

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.
CONTENTS SHOULD BE APPROVED,REPACKAGED IMMEDIATELY AND LABELED IN STRICT
CONFORMANCE WITH THE F.D & C.ACT AND REGULATIONS THEREUNDER

MANUFACTURED BY:

LABELLER CODE : 50654
LIC NO. : 25/5/2009

MANUFACTURED FOR:
SPIRIT PHARMACEUTICALS LLC
225 LINCOLN HWY, STE 205
FAIRLESS HILLS , PA 19030
PH.# 215 943 4000, FAX.#215 943 4039

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

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Y LAX DR

bisacodyl tablet, sugar coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0001
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
LACTOSE (UNII: J2B2A4N98G)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
SUCROSE (UNII: C151H8M554)	
ACACIA (UNII: 5C5403N26O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics			
Color	YELLOW (ORANGE YELLOW)	**Score**	no score
Shape	ROUND	**Size**	4mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0001-5	1 in 1 DRUM		
1		50000 in 1 BAG		
2	NDC:68210-0001-2	1 in 1 DRUM		
2		250000 in 1 BAG		
3	NDC:68210-0001-3	1 in 1 DRUM		
3		300000 in 1 BAG		
4	NDC:68210-0001-4	1 in 1 DRUM		
4		350000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/01/2010	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MISSION VIVACARE LIMITED		677604252	API MANUFACTURE, RECOVERY

Revised: 4/2010 SPIRIT PHARMACEUTICALS,LLC