

P 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.

P LAX TABLETS DR, 5 mg-SUGAR COATED: PINK

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 for children under 6 years of age

Ask a doctor before use if you have

- abdominal pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks

Ask a doctor or pharmacist before use if you are unable to swallow without chewing

When using this product

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

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

- each laxative works differently.Adults and children over 12 may need fewer tablets to get the same effect as more tablets of another brand.
- Start with one tablet and take with water.If one tablet does not produce the desired result,then try two

or three tablets daily.

- 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

- **each tablet contains** : calcium 20 mg
- do not expose to temperatures above 30°C(85°F)
- store between 20° to 25°C (68° to 77° F)

Inactive ingredients

lactose, cornstarch, povidone (K-30), sodium starch glycolate, talc, magnesium stearate, methacrylic acid copolymer, polyethylene glycol, sodium hydroxide, sucrose, acacia, gelatin, methylparaben, propylparaben, calcium sulphate dihydrate, titanium dioxide, D&C red #7 lake, FD & C Red #40; D & C Red # 27

PRINCIPAL DISPLAY PANEL - 5 mg Shipping Label

P LAX TABLETS DR, 5 mg-SUGAR COATED: PINK

Each Delayed Release Tablet Contains

(Bisacodyl 5 mg Tablets, USP)

LOT NO :

DRUM NO :

MFG. DATE :

QUANTITY : 10000

NDC NO : 68210-0002-1

EXP. DATE :

WARNING :

KEEP OUT OF THE REACH OF CHILDREN

STORE CONTROLLED ROOM TEMPERATURE 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"

P LAX TABLETS DR, 5 mg-SUGAR COATED: PINK			
Each Delayed Release Tablet Contains (Bisacodyl 5 mg Tablets,USP)			
LOT NO :		QUANTITY :	10000
DRUM NO :		NDC NO :	68210-0002-1
MFG. DATE :		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:		MANUFACTURED FOR:	
LABELLER CODE :	50654	SPIRIT PHARMACEUTICALS LLC	
LIC NO. :	25/5/2009	225 LINCOLN HWY, STE 205	
		FAIRLESS HILLS , PA 19030	
		PH.# 215 943 4000, FAX.#215 943 4039	
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P LAX DR

bisacodyl tablet, sugar coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0 709 Y6 I) (BISACODYL - UNII:10 X0 709 Y6 I)	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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LM26O6933)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0002-1	1 in 1 DRUM		
1		10000 in 1 BAG		
2	NDC:68210-0002-5	1 in 1 DRUM		
2		50000 in 1 BAG		
3	NDC:68210-0002-6	1 in 1 DRUM		
3		65000 in 1 BAG		
4	NDC:68210-0002-7	1 in 1 DRUM		
4		70000 in 1 BAG		
5	NDC:68210-0002-8	1 in 1 DRUM		
5		80000 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