BISACODYL- bisacodyl tablet, delayed release Apnar Pharma LP

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 Delayed Release Tablets USP 5 mg- Pink

Active ingredient (in each tablet)

Bisacodyl (USP) 5 mg

Purpose

Stimulant laxative

Uses

- for 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 a doctor before use if you have:

- stomach pain, nausea, or vomiting
- noticed a sudden change in bowel habits that lasts more than 2 weeks

When using this product

- it may cause stomach discomfort, faintness and cramps
- do not chew or crush tablets(s)
- do not use within 1 hour after taking antacid or milk

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after using this product.
 These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding,

ask a health care 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

- take with glass of water
- adult and children 12 years of age and over- 1 to 3 tablets in a single daily dose
- children 6 to under 12 years of age- 1 tablet in a single daily dose
- children under 6 years of age- ask a doctor

Other Information

• store at 15°-30°C (59° - 86° F).

Inactive ingredients

Lactose monohydrate, Anhydrous lactose, Pregelatinized starch, Magnesium stearate, Hypromellose, Triacetin, Talc, Methacrylic acid-ethyl acrylate copolymer (1:1) Type-A, Titanium dioxide, Triethyl citrate, D&C red no. 27, Colloidal anhydrous silica, Sodium bicarbonate, Sodium lauryl sulfate, FD&C blue no. 1, Carboxymethyl cellulose sodium, Maltodextrin, Dextrose monohydrate, Lecithin Soya.

Questions or comments?

• 1-855-642-2594

Distributed By:

APNAR PHARMA LP

CHINO, CA, 91710

Rev.: 07/2022

Compare to **Dulcolax Pink**®

active ingredient*

*This product is not maufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., owner of the registered trademark of Dulcolax Pink ®

Caution: Do not use if imprinted seal under cap is broken or missing.

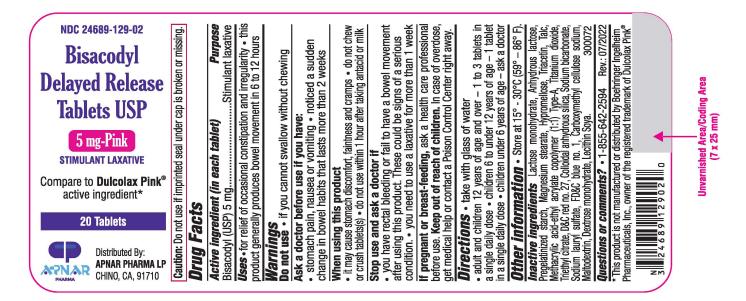
NDC 24689-129-02

Bisacodyl Delayed Release Tablets USP

5 mg- Pink

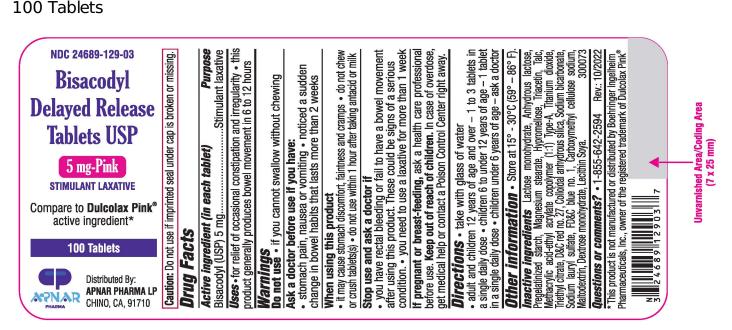
Stimulant Laxative

20 Tablets



NDC 24689-129-03

Bisacodyl Delayed Release Tablets USP
5 mg- Pink
Stimulant Laxative



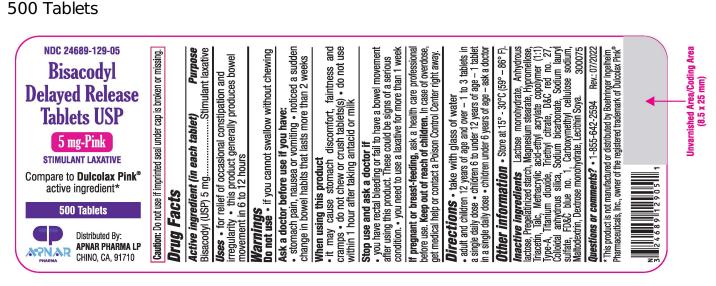
NDC 24689-129-04

Bisacodyl Delayed Release Tablets USP 5 mg- Pink Stimulant Laxative 250 Tablets



NDC 24689-129-05

Bisacodyl Delayed Release Tablets USP 5 mg- Pink Stimulant Laxative



BISACODYL bisacodyl tablet, delayed release

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24689-129
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

Inactive Ingredients	
Ingredient Name	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
TRIACETIN (UNII: XHX3C3X673)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHACRYLIC ACID-ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics			
Color	pink	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	F
Contains			

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:24689-129-	20 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2022		
NDC:24689-129- 03	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2022		
NDC:24689-129- 04	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2022		
NDC:24689-129- 05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2022		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	11/21/2022	

Labeler - Apnar Pharma LP (079568229)

Establishment			
Name	Address	ID/FEI	Business Operations
Apnar Pharma Private Limited		876730408	manufacture(24689-129), pack(24689-129), analysis (24689-129)

Revised: 11/2022 Apnar Pharma LP