PREMIER VALUE BISACODYL LAXATIVE- bisacodyl suppository suppository
Chain Drug Consortium

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.

Active Ingredient (in each Suppository)

Active Ingredient (in each Suppository) Purpose

Bisacodyl USP, 10 mg.....Laxative

Uses

Uses - For relief of occasional constipation -this product generally produces bowel movement in 1/4 hour to 1 hour

Warnings

For rectal use only.

Do not use

Do not use laxative products

-when abdominal pain, nausea, or vomiting are present - for a period longer than 1 week

Ask a doctor before use if you have

Ask a doctor before use if you have noticed a sudden change in bowel movement

burning and mild cramps

When using this product

When using this product it may cause abdominal discomfort, faintness, rectal burning, and mild cramps

Stop use and ask a doctor

Stop use and ask a doctor if rectal bleeding occurs, or you fail to have bowel movement after using a laxative. This may indicate a serious condition.

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

-adults and children 12 years of age and older - detach one suppository from the strip

-remove from wrapper before inserting into the rectum - the rectal suppository dose is one suppository per day or as directed by a doctor - children under 12 years of age consult a doctor.

Other information

Other information

store below 30°C (86°F)

Inactive ingredient

Inactive ingredient

hydrogenated vegetable oil

Purpose

Active Ingredient (in each Suppository) Purpose
Bisacodyl USP, 10 mg.....Laxative

Product Label

PREMIER VALUE BISACODYL LAXATIVE

bisacodyl suppository suppository

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-306
Route of Administration	RECTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISACODYL (UNII: 10X0709Y6I) (BISACODYL - UNII:10X0709Y6I)	BISACODYL	10 mg in 2000 mg

Inactive Ingredients

Ingredient Name	Strength
PALM KERNEL OIL (UNII: B0S90M0233)	1990 mg in 2000 mg

Product Characteristics			
Color	white	**Score**	
Shape	BULLET	**Size**	32mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-306-09	2 in 1 PACKAGE		
1	NDC:68016-306-08	40 mg in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/25/2015	

Labeler - Chain Drug Consortium (101668460)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	manufacture(68016-306)

Revised: 3/2015 Chain Drug Consortium