

BISACODYL- bisacodyl suppository
Padagis US 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.

Bisacodyl Suppositories, USP Drug Facts

Active ingredient (in each suppository)

Bisacodyl USP 10 mg

Purpose

Stimulant laxative

Use

- for temporary relief of occasional constipation and irregularity
- this product generally produces bowel movement in 15 minutes to 1 hour

Warnings

For rectal use only

Ask a doctor before use if you have

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

it may cause stomach discomfort, faintness, rectal burning and milk cramps

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative because this may indicate a serious condition
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

adults and children 12 years of age and over	1 suppository in a single daily dose. Pull apart foil. Insert suppository well into rectum, pointed end first. Retain about 15 to 20 minutes.
children 6 to under 12 years of age	½ suppository in a single daily dose
children under 6 years of age	ask a doctor

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

hydrogenated vegetable oil

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

NDC 0574-**7050**-12

Bisacodyl Suppositories, USP

10 mg

Stimulant Laxative

Easy-open plastic packets

Tapered shape for easy insertion

UNIT DOSE

12 Suppositories



BISACODYL

bisacodyl suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0574-7050
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)		BISACODYL	10 mg	
Inactive Ingredients				
Ingredient Name		Strength		
COTTONSEED OIL (UNII: H3E878020N)				
Product Characteristics				
Color	WHITE (white to cream)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0574-7050-12	12 in 1 CARTON	09/01/1990	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0574-7050-50	50 in 1 CARTON	09/01/1990	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	09/01/1990		

Labeler - Padagis US LLC (967694121)

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Padagis US LLC