

LEADER GENTLE LAXATIVE- bisacodyl suppository suppository
Major Pharmaceuticals

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.

Major[®] Bisacodyl Medicated Suppositories 100 ct

Active Ingredient (in each Suppository)

	Purpose
Bisacodyl USP, 10 mg.....	Stimulant Laxative

Uses

Uses - 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.

Do not use

Do not use - more than once per day - laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor- for a period of longer than one week unless directed by a doctor

Ask a doctor

Ask a doctor before use if you have - noticed a sudden change in bowel habits that persists over a period of two weeks

When using this product

When using this product - May cause abdominal discomfort, faintness, rectal burning, and mild cramps

Stop use and ask a doctor

Stop use and ask a doctor if you have rectal bleeding or 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. (1-800-222-1222) right away.

Directions

Adults and children 12 years of age and older
Children under 6

Children 6 to under 12 years

One suppository once daily
Ask doctor.

1/2 suppository once daily

-Detach one suppository from the strip and remove from foil - Carefully insert one suppository well into the rectum, pointed end first

- Retain about 15 to 20 minutes

Other information

Other information - Storage temperature: not to exceed 30 °C (86 °F)

- Lot No. & Exp. Date: see wrapper or box

Inactive ingredient

Inactive ingredient Hydrogenated vegetable oil

Purpose

Stimulant Laxative

Questions?

Questions? 1-724-733-7381

Product Label



LEADER GENTLE LAXATIVE

bisacodyl suppository suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6981
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	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:0904-6981-60	1 in 1 CARTON	10/17/2019	
1		1000 mg 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	10/01/2019	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	manufacture(0904-6981)

Revised: 1/2022

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