LAXATIVE- bisacodyl suppository GRAXCELL PHARMACEUTICAL, 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.

LAXATIVE SUPPOSITORIES, 70795-1010

Active Ingredient (in each suppository)

Bisacodyl, 10 mg

Purpose

Stimulant Laxative

Uses

- For relief of occasional constipation
- This product generally produces bowel movement in 15 minutes to 1 hour

Warnings

For rectal use only. May cause abdominal discomfort, faintness, rectal burning, and mild cramps.

Do not use

- more than once per day
- for a period longer than one week unless directed by a doctor
- laxative products when abdominal pain, nausea, or vomitting are present unless directed by a doctor
- if sealed film around the suppository is torn, damaged, or open.

Ask a doctor

- before use if you have noticed a sudden change in bowel habits that persist over a period of two weeks
- if you are pregnant or nursing a baby

Stop use and ask a doctor

if you have rectal bleeding or fail to have a bowel movement after using a laxative. This may indicate a serious condition.

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	Children 6 to under 12 years	Children under 6
One suppository once daily	½ suppository once daily	Ask a doctor.

- · Detach one suppository from the strip and remove from foil
- · Carefully insert one supoository well into the rectum
- Do not use more than once per day

Other information

store below 30° C (86° F)

Inactive ingredient

hydrogenated vegetable oil



100 Comfort Shaped Suppositories

Comfort Shaped

Suppositories



NDC 707951010-5
*Compare to the active ingredient in Dulcolax®
Suppositories



Laxative Suppositories

Bisacodyl USP 10mg

For Relief of Occasional Constipation

Gentle & Fast Relief

Relieves Constipation
Often In 15 Minutes to 1 Hour

Laxative Suppositories

Bisacodyl USP 10mg

For Relief of Occasional Constipation

50 Comfort Shaped Suppositories



50 Comfort Shaped Suppositories



LAXATIVE

bisacodyl suppository

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70795-1010

Route of Administration RECTAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	PICACODY (IANII 10V0700VCI) (DEACETY) DICACODY LINII D00070E41V	DIC ACODY!	10

BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)

BISACODYL

10 mg

Inactive Ingredients

Ingredient Name	Strength
migreateric manne	0

FAT, HARD (UNII: 8334LX7S21)

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:70795- 1010-8	8 in 1 BOX	03/29/2017			
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:70795- 1010-5	50 in 1 BOX	04/22/2017			
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				
3	NDC:70795- 1010-1	100 in 1 PACKAGE	04/22/2017			
3		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	03/29/2017		

Labeler - GRAXCELL PHARMACEUTICAL, LLC (056556923)

Revised: 12/2021 GRAXCELL PHARMACEUTICAL, LLC