

LAXATIVE- bisacodyl suppository
Chain Drug Marketing Association, Inc.

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.

Chain Drug Marketing Association - Bisacodyl Suppository

Active ingredient

Active ingredient (in each Suppository)

Bisacodyl, 10 mg

Purpose

Stimulant Laxative

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Uses

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

Do not use

- more than once per day
- for a period of longer than one week unless directed by a doctor
- laxative products when abdominal pain, nausea, or vomiting 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 persists 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.

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 suppository well into the rectum
- Do not use more than once per day

Other information

- Store at room temperature: 15° - 30° C (59° - 86° F) Do not exceed 30° C (86° F)
- Individually sealed for your protection. Do not use if foil is torn or open.

Inactive ingredients

hydrogenated vegetable oil

Warnings

For rectal use only.

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

For Relief of Occasional Constipation

NDC 63868-328-08

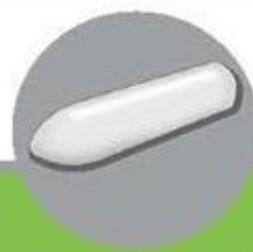


*Compare to the active ingredient in Dulcolax®

Laxative Suppositories

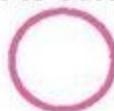
Gentle & Fast Relief

Bisacodyl USP 10mg
Relieves Constipation Often In
15 Minutes to 1 Hour



8 Comfort Shaped Suppositories

TAMPER EVIDENT: Individually sealed in foil for your protection. Do not use if foil is torn or open.



Laxative Suppositories

Drug Facts

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Inactive ingredient hydrogenated vegetable oil

*This product is not manufactured or distributed by Boehringer Ingelheim Consumer Health Care, owner of the registered trademark, Dulcolax®.



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LAXATIVE

bisacodyl suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-328
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	10 mg

Inactive Ingredients

Ingredient Name		Strength		
FAT, HARD (UNII: 8334LX7S21)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-328-08	8 in 1 BOX	05/18/2021	
1		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	12/21/2007		

Labeler - Chain Drug Marketing Association, Inc. (011920774)

Registrant - Acino Products, LLC (019385518)

Establishment

Name	Address	ID/FEI	Business Operations
Acino Products, LLC		019385518	manufacture(63868-328)

Revised: 5/2021

Chain Drug Marketing Association, Inc.