

BISACODYL - bisacodyl suppository
Cardinal Health

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.

Leader Bisacodyl Suppositories

Active ingredient (in each suppository)

Bisacodyl USP, 10mg

Purpose

Stimulant Laxative

Uses

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

Warnings

For rectal use only.

Do not use unless directed by a doctor

- if abdominal pain, nausea or vomiting are present
- for longer than 1 week

Ask a Doctor before use if you have

noticed a sudden change in bowel habits that lasts over a period of 2 weeks

When using this product

it may cause abdominal discomfort, flatness, rectal burning and mild cramps

Stop use and ask a doctor if

you have rectal bleeding or fail to have a bowel movement after using this product. These may indicate a serious condition.

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 (1-800-222-1222)

right away.

Directions

- detach one suppository from the strip
- remove wrapper before inserting into rectum
- carefully insert one suppository well into the rectum, pointed end first
- retain about 15 to 20 minutes

adults and children 12 years of age and over - 1 suppository once daily

children 6 to under 12 years of age - 1/2 suppository once daily

children under 6 - do not use

Other information

- Store at room temperature do not to exceed 30°C (86°F)
- Lot No. & Exp. Date: see wrapper or box

Inactive ingredients

hydrogenated vegetable oil

Questions or comments?

(800) 492-5988

Leader Bisacodyl Suppositories

LeaderBisSupp.jpg



active ingredient*

16 SUPPOSITORIES
(COMFORT SHAPED)
DO NOT SWALLOW

100% Money
Back Guarantee

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

Questions or comments?

1-800-492-5988

Inactive ingredient

hydrogenated vegetable oil

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

■ **Other information** ■ Store at room temperature. Do not exceed 30° C (86° F)

Drug Facts (continued)

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adults and children 12 years of age and over	1 suppository once daily

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

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

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■ if abdominal pain, nausea or vomiting are present ■ for longer than 1 week

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Active ingredient (in each suppository) Biscodyl, USP 10 mg.....Stimulant Laxative

Purpose

Drug Facts

DO NOT USE IF WRAPPER IS TORN OR OPEN.

The product package shown above represents a sample of that currently in use. Additional packaging may also be available.

Bisacodyl Suppositories

Distributed by

Major Pharmaceuticals

Livonia, MI 48152

BISACODYL

bisacodyl suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0573
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
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0573-2	4 in 1 CARTON	05/19/2021	
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0573-1	1 in 1 CARTON	05/19/2021	
2		4 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	not 224	05/19/2021	

final	part 554	05/19/2021	
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Labeler - Cardinal Health (063997360)

Registrant - DSC Laboratories, Inc. (097807374)

Establishment

Name	Address	ID/FEI	Business Operations
DSC Laboratories, Inc.		097807374	manufacture(70000-0573)

Revised: 6/2021

Cardinal Health