

LEADER GENTLE LAXATIVE- bisacodyl suppository suppository
Cardinal Health, 110 dba LEADER

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® Gentle Laxative 4 count

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

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100% Money Back Guarantee Return to place of purchase if not satisfied.

LEADERTM

NDC 70000-0451-1

Gentle Laxative

Bisacodyl USP Suppository, 10 mg | Stimulant Laxative
 Gentle, Predictable, Fast Relief



Actual Size

4 SUPPOSITORIES (COMFORT SHAPED)
 DO NOT SWALLOW

COMPARE TO DULCOLAX[®]
 active ingredient*

100% Money Back Guarantee

*This product is not manufactured or distributed by Chatham Inc., owner of the registered trademark Dulcolax[®].

Drug Facts (continued)
 ■ you fail to have a bowel movement after using a laxative. This 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 the suppository from the strip
 ■ Remove from foil. Carefully insert one suppository well in to the rectum, pointed end first
 ■ Retain about 15 to 20 minutes
 adults and children 12 years of age and older 1 suppository once daily
 children 6 to 12 years of age and older ½ suppository once daily
 children under 6 years ½ suppository once daily
 children under 6 years ask a doctor.
Other information
 ■ Store at room temperature. Do not exceed 30°C (86°F)
 ■ Lot No. & Exp. Date: see wrapper or box
Inactive ingredient hydrogenated vegetable oil
Questions? 1-724-733-7381

Drug Facts
Active ingredient (in each suppository) Bisacodyl USP, 10 mg Stimulant Laxative
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
 ■ 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 before use if you have noticed a sudden change in bowel habits that persists over a period of two weeks.
When using this product may cause abdominal discomfort, flatness, rectal burning, and mild cramps
 ■ you have rectal bleeding
Stop use and ask a doctor if

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 DUBLIN, OHIO 43017
 www.myleader.com
 1-800-200-6313

CIN 5484613 REV. 1/19
 0 96295 13634 0

INDIVIDUALLY SEALED FOR YOUR PROTECTION. DO NOT USE IF WRAPPER IS TORN OR OPEN.

LEADER GENTLE LAXATIVE

bisacodyl suppository suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0451
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
PALM KERNEL OIL (UNII: B0S90M0233)	

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:70000-0451-1	1 in 1 CARTON	01/24/2019	
1	NDC:70000-0451-4	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 final	part334	01/24/2019	

Labeler - Cardinal Health, 110 dba LEADER (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	manufacture(70000-0451)

