BISACODYL - bisacodyl suppository CARDINAL HEALTH, 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.

Bis acodyl Suppositories

ACTIVE INGREDIENT (in each suppository)

Bisacodyl USP, 10 mg

PURPOSE

Laxative

USES

For the relief of occasional constipation. Bowel movement is generally produced in 15 minutes to 1 hour.

WARNINGS

For rectal use only

Do not use

laxative products for a period longer than one week unless directed by a doctor

Ask a doctor before use if you have

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits that lasts longer than 2 weeks

Stop use and ask a doctor

if rectal bleeding occurs or 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 SECTION

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

DIRECTIONS

• Remove foil. Insert suppository well into rectum touching the bowel wall. Retain about 15 to 20 minutes.

adults and children 12 years and over	1 suppository once daily	
children 6 years to under 12 years	1/2 suppository once daily	
children under 6 years	ask a doctor	

• In the presence of anal fissures or hemorrhoids, suppositories should be coated at the tip with

petroleum jelly.

OTHER INFORMATION

Store at room temperature

INACTIVE INGREDIENT

hydrogenated vegetable oil

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 37205-102-53
LEADER®
BISACODYL SUPPOSITORIES
LAXATIVE
FOR PROMPT RELIEF OF CONSTIPATION
12 BISACODYL SUPPOSITORIES 10 MG EACH
Compare to Dulcolax® active ingredient*
Satisfaction Guaranteed

DISTRIBUTED BY CARDINAL HEALTH JN 2372126

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

Inactive ingredient hydrogenated vegetable oil

All Leader® Brand products are

raiseant of Bookinger by child in Pharmacerites b, be. "This pooled is not menufactured or distributed by behinder ingeliein Pharmaceulicus, inc., distributor or anutadurer di Dillicollum[®] Dillicollum[®] is a registerer

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LEADER®

Keep out of reach of children. If swellowed, get medical help or contact a Poison Control Center right away.

pregnant or breast-feeding, ask a health professional before

Directions

Stop use and ask a doctor if rectal bleeding occurs or you fail to have a bowel movement after using a laxative. This may indicate a abdominal pain, nausea or vomiting
a sudden change in bowel habits that lasts longer than 2 weeks by a doctor

Do not use For rectal use only Warnings Active ingredient (in each suppository) Drug Facts

Purpose

Bisacodyl USP, 10 mg

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Laxative

NDC 37205-102-53



BISACODYL SUPPOSITORIES



FOR PROMPT RELIEF OF CONSTIPATION

12 Bisacodyl Suppositories • 10 mg each

TAMPER-EVIDENT. For your safety, suppositories are packaged in tamper-evident sealed foil. Do not use if foil is torn or open.

UPC 0-96295-10573 Keyline does not print

BISACODYL

bisacodyl suppository

Product Information

Product Type HUMAN OTC DRUG Item Code (Source)

RECTAL Route of Administration

NDC:37205-102

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Bisacodyl (UNII: 10 X0 70 9 Y6 I) (Bisacodyl - UNII: 10 X0 70 9 Y6 I)	Bisacodyl	10 mg	

	Inactive Ingredients
ı	8

Ingredient Name Strength

Hydrogenated Palm Kernel Oil (UNII: FM8 D1RE2VP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-102-53	12 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/10/1997	

Labeler - CARDINAL HEALTH, INC. (097537435)

Registrant - G&W Laboratories, Inc. (001271188)

Establishment				
Name	Address	ID/FEI	Business Operations	
G&W Laboratories, Inc.		001271188	MANUFACTURE	

Revised: 3/2012 CARDINAL HEALTH, INC.