

BISACODYL- bisacodyl suppository
Rising Pharma Holdings, 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.

Bisacodyl USP Suppositories 10 mg

Drug Facts

Active ingredient (in each suppository)

Bisacodyl USP, 10 mg

Purpose

Stimulant Laxative

Use

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

Warnings

For rectal use only

Ask a doctor before use if you have

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

When using this product you may experience stomach discomfort, faintness, rectal burning and mild cramps

Stop use and ask a doctor if

- you need to use a laxative product for longer than one week
- you have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition.

If pregnant or breast-feeding, ask health professional before use.

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 over	1 suppository in a single daily dose. Peel open plastic. Insert suppository well into rectum, pointed end first. Retain about 15 to 20 minutes
children 6 to under 12 years	1/2 suppository in a single daily dose
children under 6 years	Do not use

Other information

- store at 20-25°C (68-77°F)
- if suppository softens prior to use, may be placed in refrigerator for short time

Inactive ingredient hard fat

Questions or Comments? Call 1-844-474-7464

**TAMPER EVIDENT: DO NOT USE IF SEALED WRAPPER AROUND
SUPPOSITORIES IS BROKEN OR MISSING**

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Made in India

CODE NO.: MH/DRUGS/25-KD/724

Issued: 08/2023

NDC 57237-327-21 (3 blisters of 4 suppositories)

Bisacodyl USP Suppositories 10 mg

Stimulant Laxative

Gentle, Predictable, Fast Relief

DO NOT SWALLOW

SNK

LOT: XXXXXXXX
EXP: YYYYMM



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UNVARNISHED AREA FOR OPZ

BISACODYL USP
10 mg

Stimulant Laxative

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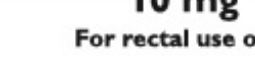

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Stimulant Laxative
BISACODYL USP
10 mg

Distributed by:
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NDC 57237-327-04 (4 suppositories in 1 blister pack)

Front Foil

		
	<p>BISACODYL USP 10 mg For rectal use only</p>	
	<p>NDC 57237-327-04</p>	<p>Code No.: MH/DRUGS/25-KD/724</p>
	 <p>BISACODYL USP 10 mg For rectal use only</p>	
	<p>NDC 57237-327-04</p>	<p>A 12004710</p>

Back Foil

<p>Dist. By: Rising Pharma Holdings, Inc. Store at 20-25°C (68-77°F)</p>	
<p>Dist. By: Rising Pharma Holdings, Inc. Store at 20-25°C (68-77°F)</p>	<p>A 12004711</p>

BISACODYL

bisacodyl suppository

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:57237-327

Route of Administration	RECTAL
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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)	

Product Characteristics

Color	white	Score	
Shape	BULLET	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-327-21	3 in 1 CARTON	08/24/2023	
1	NDC:57237-327-04	4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:57237-327-03	6 in 1 CARTON	08/24/2023	
2	NDC:57237-327-51	5 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	08/24/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Establishment

Name	Address	ID/FEI	Business Operations
Bliss GVS Pharma Limited		675630493	manufacture(57237-327) , analysis(57237-327) , pack(57237-327)