

PROCTOZONE-B- bisacodyl suppository
Rising Pharma Holdings, Inc.

Proctozone-B™ 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, INDIVIDUALLY SEALED FOR YOUR PROTECTION

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Made in India

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

Issued: 09/2024

NDC 57237-337-21 (3 blisters of 4 suppositories)

Proctozone-B™

Bisacodyl (USP) 10 mg Suppositories

MEDICATED LAXATIVE SUPPOSITORY

Gentle, Predictable Relief

DO NOT SWALLOW

GTIN No. 00357237337219
 SR No.: XXXXXXXXXX
 LOT: XXXXXXXX
 EXP: YYYYYM



UNVARNISHED AREA FOR
OPZ

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Proctozone-B™
 Bisacodyl (USP) 10 mg Suppositories
MEDICATED LAXATIVE SUPPOSITORY
 Gentle, Predictable Relief
 Easy-to-treat, comfort shaped PROCTOZONE-B™ suppositories provide relief from constipation that takes to work within 9 minutes to 1 hour when inserted rectally.
 DO NOT SWALLOW
 FAST RELIEF IN MINUTES

13011210

Proctozone-B™
 Bisacodyl (USP) 10 mg Suppositories
MEDICATED LAXATIVE SUPPOSITORY
 Gentle, Predictable Relief

- Convenient, No-mess
- Hygienic, Travel-Friendly

12
COMFORT SHAPED SUPPOSITORIES

Rising®
 HEALTH
 Distributed by:
 Rising Pharma Holdings, Inc.
 East Brunswick, NJ 08816
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 CODE NO: MH/DRUGS/25-KD/724
 Issued: 09/2024

N 3 57237 33721 9

NDC 57237-337-21

FAST RELIEF IN MINUTES

DO NOT SWALLOW

NDC 57237-337-04 (4 suppositories in 1 blister pack)
Front Foil

	 Proctozone-B™ <i>Bisacodyl (USP) 10 mg Suppositories</i> For rectal use only	
	NDC 57237-337-04	Code No.: MH/DRUGS/25-KD/724
	 Proctozone-B™ <i>Bisacodyl (USP) 10 mg Suppositories</i> For rectal use only	
	NDC 57237-337-04	A 12004982

NDC 57237-337-04 (4 suppositories in 1 blister pack)

Back Foil

	Dist. By: Rising Pharma Holdings, Inc.	N 3  2 57237 33704
	Store at 20-25°C (68-77°F)	N 3  2 57237 33704
	Dist. By: Rising Pharma Holdings, Inc.	N 3  2 57237 33704
A 12004981	Store at 20-25°C (68-77°F)	N 3  2 57237 33704
		N 3  2 57237 33704

PROCTOZONE-B

bisacodyl suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-337
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)	

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:57237-337-21	3 in 1 CARTON	12/01/2024	
1	NDC:57237-337-04	4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:57237-337-03	6 in 1 CARTON	02/01/2025	
2	NDC:57237-337-51	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 Drug	M007.60	12/01/2024	

Labeler - Rising Pharma Holdings, Inc. (116880195)