

**BISACODYL- bisacodyl suppository**  
**Acino Products, LLC**

*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.*

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**ACINO - BISACODYL LAXATIVE SUPPOSITORIES**

**Active Ingredients (per suppository)**

Bisacodyl USP, 10 mg

**Purpose**

Laxative

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

**Uses**

- for relief of occasional constipation
- this product usually produces bowel movement in 1/4 to 1 hour

**Warnings**

For rectal use only.

**Do not use laxative products**

- when abdominal pain, nausea or vomiting are present
- for a period longer than one week

**Ask a doctor before use if you have**

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

**When using this product**

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

**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.

**Directions**

- adults and children 12 years of age and older
- detach one suppository from the strip
- remove from wrapper before inserting into the rectum
- the rectal suppository dose is one suppository per day or as directed by a doctor
- children under 12 years of age consult a doctor

**Other information**

store below 30° C (86° F)

**Inactive ingredient**

hydrogenated vegetable oil

Acino  
Products

# ***BISACODYL*** ***Laxative Suppositories***



NDC 58794-102-18  
COMPARE TO THE  
ACTIVE INGREDIENT IN  
DULCOLAX<sup>®</sup> SUPPOSITORIES\*

# ***BISACODYL*** ***Laxative Suppositories***

FAST RELIEF OF TEMPORARY CONSTIPATION OFTEN  
IN 15 MINUTES TO 1 HOUR

**18 SUPPOSITORIES (10 mg each)**

## Drug Facts

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**Uses** ■ for relief of occasional constipation ■ this product generally produces bowel movement in 1/4 to 1 hour

### Warnings

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**Ask a doctor before use if you have noticed a sudden change in bowel habits that persist over a period of 2 weeks**

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

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

### Directions

■ adults and children 12 years of age and older ■ detach one suppository from the strip  
■ remove from wrapper before inserting into the rectum ■ the rectal suppository dose is one suppository per day or as directed by a doctor ■ children under 12 years of age consult a doctor

### Other information

store below 30° C (86° F)

### Inactive ingredient

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TAMPER-EVIDENT: FOR YOUR SAFETY, SUPPOSITORIES ARE PACKED IN TAMPER-EVIDENT SEALED WRAPPER. DO NOT USE IF WRAPPER IS TORN OR OPEN.



\*This product is not manufactured or distributed by Bayer/Ingelheim Consumer Healthcare Products Inc., owner of the registered trademark Dulcolax®

## BISACODYL

bisacodyl suppository

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68784-102
Route of Administration	RECTAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)		BISACODYL	10 mg	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
FAT, HARD (UNII: 8334LX7S21)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68784-102-08	8 in 1 BOX	05/18/2021	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:68784-102-12	12 in 1 BOX	05/18/2021	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:68784-102-16	16 in 1 BOX	05/18/2021	
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:68784-102-01	100 in 1 BOX	05/18/2021	
4		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	01/01/2005		

**Labeler** - Acino Products, LLC (019385518)

### Establishment

Name	Address	ID/FEI	Business Operations
Acino Products, LLC		019385518	manufacture(68784-102)

Revised: 5/2021

Acino Products, LLC