

**BISAC-10 BISACODYL STIMULANT LAXATIVE- bisacodyl suppository**  
**GALEN PHARMACEUTICALS LIMITED**

*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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**BISAC-10**

**Drug Facts**

**Active ingredient (in each suppository)**

Bisacodyl 10 mg

**Purpose**

Laxative

**Uses**

- for relief of occasional constipation
- this product generally 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 unless directed by a doctor
- laxative products for a period longer than 1 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 2 weeks

**When using this product**

it may cause • abdominal discomfort • faintness  
• rectal burning • mild cramps  
• store at temperatures not above 86°F (30°C)

**Stop use and ask a doctor if**

- rectal bleeding
- failure to have a bowel movement which occurs after use of a laxative may indicate a serious condition.

**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: 1 suppository, once daily
- suppository should be moistened with water before inserting.

**Other information**

- store in well closed containers

**Inactive ingredients**

polyethylene glycol

**Questions? +1-863-434-1782**

**You may also report serious side effects to this phone number.**

Mon - Sun: 24/7

**Bisacodyl Stimulant Laxative****Suppositories For Adults**

FOR RECTAL USE ONLY

**Manufactured by:****Galen Pharmaceuticals Ltd.**

334/5 GIDC Estate Waghodia,  
Vadodara, Gujarat, India, 391760

**Country of Origin: India**

Web: [www.galenltd.com](http://www.galenltd.com)

**Packaging**

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 Pharmaceuticals Ltd.

Country of Origin: India

Mfg.Lic.No.: GUJ/DRUGS/G-1023

Web: www.galenltd.com

FOR RECTAL USE ONLY

(Inclusive of all Taxes)

Batch No.  
 Mfg.Date  
 Exp.Date

**BISAC-10**

**Bisacodyl Stimulant Laxative**

Suppositories For Adults

**12 Suppositories**



**BISAC-10**

## BISAC-10 BISACODYL STIMULANT LAXATIVE

bisacodyl suppository

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81440-102
<b>Route of Administration</b>	RECTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>BISACODYL</b> (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	10 mg
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### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>	BULLET (Cylindrical)	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81440-102-12	1 in 1 BOX	02/15/2021	
1		12 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	02/15/2021	

**Labeler** - GALEN PHARMACEUTICALS LIMITED (916655764)

### Establishment

Name	Address	ID/FEI	Business Operations
GALEN PHARMACEUTICALS LIMITED		916655764	manufacture(81440-102)

Revised: 4/2023

GALEN PHARMACEUTICALS LIMITED