

**LAXATIVE - bisacodyl suppository**  
**GRAXCELL PHARMACEUTICAL, 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.*

-----

**Active Ingredient (in each suppository)**

Bisacodyl, 10 mg

**Purpose**

Stimulant Laxative

**Uses**

- For relief of occasional constipation
- This product generally produces bowel movement in 15 minutes to 1 hour

**Warnings**

**For rectal use only.** □May cause abdominal discomfort, faintness, rectal burning, and mild cramps.

**Do not use**

- more than once per day
- for a period longer than one week unless directed by a doctor
- laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor
- if sealed film around the suppository is torn, damaged, or open.

**Ask a doctor**

- before use if you have noticed a sudden change in bowel habits that persist over a period of two weeks
- if you are pregnant or nursing a baby

**Stop use and ask a doctor**

if you have rectal bleeding or fail to have a bowel movement after using a laxative. This 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 and older	Children 6 to under 12 years	Children under 6
One suppository once daily	½ suppository once daily	Ask a doctor.

- Detach one suppository from the strip and remove from foil

- Carefully insert one suppository well into the rectum
- Do not use more than once per day

### Other information

store below 30° C (86° F)

### Inactive ingredient

hydrogenated vegetable oil

### Principal Display panel

GRAXCELL PHARMACEUTICAL, LLC.

NDC 70795-1010-8/70795-1010-5/70795-1010-1

\*Compare to active ingredient in Dulcolax Suppositories

Laxative Suppositories Bisacodyl USP 10mg

For Relief of Occasional Constipation

Gentle and fast Relief

Relieves Constipation Often In 15 Minutes to 1 Hour

8 Comfort Shaped Suppositories





**GRAXCELL**  
PHARMACEUTICAL, LLC.

NDC 707951010-5  
\*Compare to the  
active ingredient  
in Dulcolax®  
Suppositories



**GRAXCELL**  
PHARMACEUTICAL, LLC.

# Laxative Suppositories

Bisacodyl USP 10mg

For Relief of  
Occasional Constipation

**Gentle & Fast Relief**

Relieves Constipation  
Often In 15 Minutes to 1 Hour



**50** Comfort Shaped Suppositories

# Laxative Suppositories

Bisacodyl USP 10mg

For Relief of  
Occasional Constipation

**50** Comfort Shaped  
Suppositories



**GRAXCELL**  
PHARMACEUTICAL, LLC.

NDC 70795-1010-1

\*Compare to the active ingredient  
in Dulcolax® Suppositories



**GRAXCELL**  
PHARMACEUTICAL, LLC.

# Laxative Suppositories

For Relief of  
Occasional Constipation

Bisacodyl USP 10mg

Gentle & Fast Relief

Relieves Constipation Often In 15 Minutes to 1 Hour



# Laxative Suppositories

Bisacodyl USP 10mg

For Relief of  
Occasional Constipation

100  
Comfort Shaped  
Suppositories

100 Comfort Shaped Suppositories

## LAXATIVE

bisacodyl suppository

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70795-1010
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)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70795-1010-8	8 in 1 BOX	03/29/2017	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70795-1010-5	50 in 1 BOX	04/22/2017	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:70795-1010-1	100 in 1 PACKAGE	04/22/2017	
3		1 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	03/29/2017	

**Labeler** - GRAXCELL PHARMACEUTICAL, LLC (056556923)

**Registrant** - GRAXCELL PHARMACEUTICAL, LLC (056556923)

Revised: 6/2017

GRAXCELL PHARMACEUTICAL, LLC