

**AVEDANA GENTLE LAXATIVE- bisacodyl suppository**  
**Unipack LLC**

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**Avedana® Bisacodyl Suppository**

**Active Ingredient (in each Suppository)**

	Purpose
Bisacodyl USP, 10 mg.....	Stimulant Laxative

**Uses**

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

**Warnings**

For rectal use only.

**Do not use**

Do not use - more than once per day - for a period of longer than one week unless directed by a doctor - laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor

**Ask a doctor**

Ask a doctor before use if you have - noticed a sudden change in bowel habits that persists over a period of two weeks

**When using this product**

When using this product - May cause abdominal discomfort, faintness, rectal burning, and mild cramps

**Stop use and ask a doctor**

Stop use and ask a doctor if you have rectal bleeding or fail to have bowel movement after using a laxative. This may indicate a serious condition

**If pregnant or breast-feeding**

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

**Keep out of reach of children**

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 under 6

Children 6 to under 12 years

One suppository once daily  
Ask doctor.

1/2 suppository once daily

-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**

Other information - Store at room temperature: 15 ° - 30 °C (59 ° - 86 °F). Do not exceed 30 °C (86 °F) - Individually sealed for your protection. Do not use if foil is torn or open

**Inactive ingredient**

Inactive ingredient Hydrogenated vegetable oil

**Purpose**

Stimulant Laxative

**Label**

**Avedana<sup>®</sup> Bisacodyl Suppositories**



## AVEDANA GENTLE LAXATIVE

bisacodyl suppository

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-460
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
PALM KERNEL OIL (UNII: B0S90M0233)	

**Product Characteristics**

Color	white	Score	
Shape	BULLET	Size	32mm
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43749-460-16	4 in 1 CARTON	09/17/2017	
1	NDC:43749-460-17	4 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	09/17/2017	

**Labeler** - Unipack LLC (009248480)**Registrant** - Unipack LLC (116015769)**Establishment**

Name	Address	ID/FEI	Business Operations
Unipack LLC		009248480	manufacture(43749-460)