

AVEDANA GENTLE LAXATIVE- bisacodyl suppository
Unipack LLC

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[®] 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 (009248480)**Establishment**

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