

BISAC-EVAC - bisacodyl suppository
Cosette Pharmaceuticals, Inc.

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.

BISAC-EVAC™
Bisacodyl USP 10 mg

ACTIVE INGREDIENT (in each suppository)

Bisacodyl USP, 10 mg

PURPOSE

Laxative

USES

For the relief of occasional constipation.
Bowel movement is generally produced in 15 minutes to 1 hour.

WARNINGS

For rectal use only

Do not use laxative products for a period longer than one week unless directed by a doctor

Ask a doctor before use if you have

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits that lasts longer than 2 weeks

Stop use and ask a doctor if rectal bleeding occurs or you fail to have a bowel movement after using a laxative. These may be signs of 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

- see chart below for dose
- remove foil wrapper
- insert suppository well up into the rectum as indicated, and retain it about 15 to 20 minutes

adults and children 12 years and over	1 suppository once daily.
children 6 years to under 12 years	1/2 suppository once daily
children under 6 years	ask a doctor

• In the presence of anal fissures or hemorrhoids, suppositories should be coated at the tip with petroleum jelly.

OTHER INFORMATION

Store at room temperature

INACTIVE INGREDIENT

hydrogenated vegetable oil

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

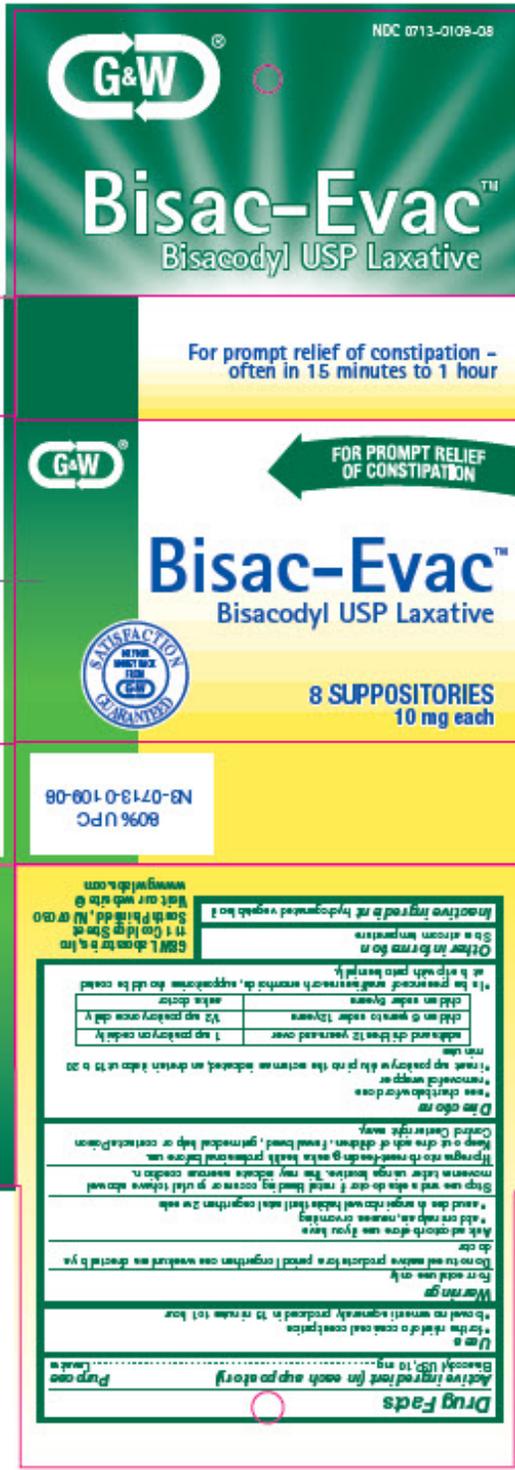
NDC 0713-0109-08

G&W®

BISAC-EVAC™

Bisacodyl USP LAXATIVE

8 SUPPOSITORIES 10 mg each



BISAC-EVAC			
bisacodyl suppository			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0713-0109
Route of Administration	RECTAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
BISACODYL (UNII: 10 X0 709 Y6I) (DEACETYLBISACODYL - UNII:R090 78 E41Y)		BISACODYL	10 mg	
Inactive Ingredients				
Ingredient Name			Strength	
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0109-12	12 in 1 CARTON; Type 0: Not a Combination Product	05/22/1991	
2	NDC:0713-0109-01	100 in 1 CARTON; Type 0: Not a Combination Product	05/22/1991	
3	NDC:0713-0109-08	8 in 1 CARTON; Type 0: Not a Combination Product	05/22/1991	
4	NDC:0713-0109-50	50 in 1 CARTON; Type 0: Not a Combination Product	05/22/1991	
5	NDC:0713-0109-05	500 in 1 CARTON; Type 0: Not a Combination Product	05/22/1991	
6	NDC:0713-0109-10	1000 in 1 CARTON; Type 0: Not a Combination Product	05/22/1991	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	05/22/1991		

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals, Inc.		116918230	analysis(0713-0109) , manufacture(0713-0109) , label(0713-0109) , pack(0713-0109)

Revised: 8/2019

Cosette Pharmaceuticals, Inc.