GENTLE LAXATIVE BISACODYL- gentle laxative bisacodyl suppository NeilMed 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.

NeilMed Gentle Laxative Suppositories Bisacodyl USP 10mg

Drug Facts: Active ingredient

(in each suppository) Bisacodyl 10 mg

Drug facts

Purpose Bisacodyl 10 mg Stimulant Laxative

Uses

- for relief of occasional constipation
- this product generally produces bowel movement in 15 to 60 minutes

Warnings

■ For rectal use only

Do not use

- when abdominal pain, nausea or vomiting are present
- for a period longer than 1 week

Ask a doctor before use

if you have noticed a sudden change in bowel habits that lasts over a period of 2 weeks

When using this product

it may cause abdominal discomfort, faintness, rectal bleeding and mild cramps

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after using this product. This may indicate 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

- detach one suppository from the strip
- remove wrapper before inserting into the rectum

adults and children 12 and over: 1 suppository once daily children 6 to under 12 years: ½ suppository once daily children under 6 years: do not use

Other information

- Store at room temperature. Do not exceed 30° C (86° F)
- Lot No. & Exp. Date: see wrapper or box

Inactive ingredient

hydrogenated vegetable oil

Questions?

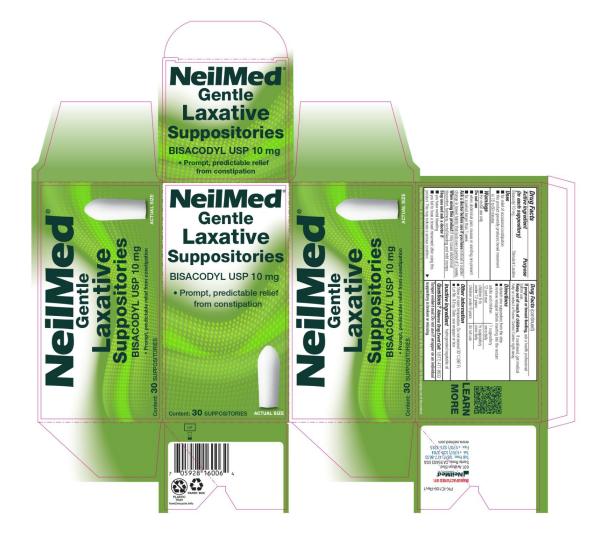
Adverse Drug Event Call: 1(877) 477-8633

Tamper evident seal:

Do not use if wrapper on an individual suppository is broken or missing. Prompt, predictable relief from constipation

Package Label





GENTLE LAXATIVE BISACODYL

gentle laxative bisacodyl suppository

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:13709-321

Route of Administration RECTAL

Active Ingredient/Active Moiety

I	Ingredient Name	Basis of Strength	Strength
l	BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	10 mg

Inactive Ingredients

Ingredient Name Strength

PALM KERNEL OIL (UNII: B0S90M0233)

Packaging

gg				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:13709-321-	5 in 1 CARTON	08/24/2023		
L	6 in 1 BLISTER PACK			
L	1 in 1 CAPSULE; Type 0: Not a Combination Product			

Marketing Information

NeilMed Pharmaceuticals Inc.

Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not pa	art334	08/24/2023	

Labeler - NeilMed Pharmaceuticals Inc (799295915)

Establishment						
Name	Address	ID/FEI	Business Operations			

Revised: 8/2023 NeilMed Pharmaceuticals Inc

799295915

manufacture(13709-321)