

GENTLE LAXATIVE- gentle laxative tablet
Healthlife of USA

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.

Gentle Laxative
Bisacodyl 5mg

Drug Facts

Gentle Laxative

Purpose

Stimulant Laxative

Active Ingerient (in each tablet)

Bisacodyl 5mg

Uses

- For temporary relief of occasional constipation and irregularity
- This product generally produces a bowel movement in 6 to 12 hours

Warnings

Do not use

- If you cannot swallow without chewing

Ask a doctor before use if you have

- stomach pain, nausea or vomiting
- a sudden change in bowel habits that last more than 2 weeks

When using this product

- Do not chew or crush tablet(s)
- Do not use within 1 hour after taking an antacid or milk
- It may cause stomach discomfirt, faintness and cramps

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition
- you need to use a laxative for more than 1 week

If pregnant or breast-feeding

Ask a health professional before use

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

- Take with a glass of water
- Adults and children 12 years of age and over : Take 1 to 3 tablets in a single daily dose
- Children 6 to under 12 years of age: Take 1 tablet in a single daily dose
- Children under 6 years of age: Ask a doctor

Other Information

- Store at controlled room temperature 20°- 25°C (68°- 77°F)
- Read all product information before using
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Inactive ingredients

- Colloidal silicon dioxide
- Croscarmellose sodium
- Dicalcium phosphate
- FD&C Blue#1
- FD&C Blue#2
- Magnesium Stearate
- Microcrystalline cellulose
- Polyethylene glycol
- Polyvinyl alcohol
- Talc
- Titanium dioxide

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM - 5PM EST or www.healthlifeofusa.com

Gentle Laxative

Bisacodyl 5 mg Compare to Dulcolax® Laxative active ingredients

Distributed by:

Healthlife of USA LLC Rahway NJ 07065 www.healthlifeofusa.com



GENTLE LAXATIVE

gentle laxative tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-116
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0709 Y61) (DEACETYLBISACODYL - UNII:R09078 E41Y)	BISACODYL	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6 XBU4)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-116-24	1 in 1 CARTON	05/31/2017	
1		24 in 1 BOTTLE; 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	05/31/2017	

Labeler - Healthlife of USA (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
Healthlife of USA		079656178	repack(69517-116)

Establishment

Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc.		037052099	manufacture(69517-116) , pack(69517-116)