HEB GENTLE LAXATIVE- bisacodyl suppository
H E B

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.

DRUG FACTS

Active ingredient

Bisacodyl USP, 10 mg

Purpose

Stimulant Laxative

Uses

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

Warnings

For rectal use only.

- stomach pain, nausea or vomiting
- noticed a sudden change in bowel habits that persists over a period of two weeks

When using this product

May cause abdominal discomfort, faintness, rectal burning, and mild cramps

Stop use and ask a doctor if

- if you have rectal bleeding or fail to have bowel movement after using a laxative. This may indicate 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

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and older	Children 6 to under 12 years	Children under 6
One suppository once daily	1/2 suppository once daily	Ask doctor.

-Detach one suppository from the strip and remove from foil - Carefully insert one suppositry well into the rectum

-Do not use more than once per day

Other Information

- do not store above 30°C (86°F)

Inactive Ingredients

hydrogenated vegetable oil

HEB GENTLE LAXATIVE

bisacodyl suppository

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37808-353

Route of Administration	RECTAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	10 mg in 2000 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FAT, HARD (UNII: 8334LX7S21)	1990 mg in 2000 mg

Product Characteristics			
Color	white	**Score**	
Shape	BULLET	**Size**	34mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-353-08	2 in 1 CARTON	11/16/2015	
1		40 mg 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 not final	part334	02/13/2015	

Labeler - H E B (007924756)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(37808-353) , repack(37808-353)

Establishment

Name	Address	ID/FEI	Business Operations
Torrent Pharma Inc.		116943196	manufacture(37808-353)