

LAXATIVE- bisacodyl tablet, delayed release
HHH PHARMA USA LLC

Active ingredient (in each tablet)

Bisacodyl USP, 5 mg

Purpose

Laxative

Uses

- for temporary relief of occasional constipation and irregularity
- this product generally produces 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 lasts 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 discomfort, faintness, and cramps

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a 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 (1-800-222-1222) right away.

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	1 tablets once a day
children under 6 years	ask a doctor

Other information

- store at controlled room temperature 20°-25°C (68°-77°F)
- read all product information before use.

Inactive ingredients

Colloidal silicon dioxide, hypromellose-5, magnesium stearate, maltodextrin, methacrylic acid, microcrystalline cellulose, neelicert FD&C yellow 10 Al Lake, neelicert FD&C yellow 6 Al Lake, PEG 400, sodium starch glycolate, talc, titanium dioxide, triethyl citrate.

Questions or comments?

Call + 1-848-235-5293

Monday through Friday 9AM – 5PM EST

Principal Display Panel

Drug Facts (Continued)

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 (1-800-222-1222) right away.

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NDC 83586-116-01

*Compare to the active ingredient in Dulcolax®

ENTERIC COATED BISACODYL

LAXATIVE

Bisacodyl 5 mg

Gentle and Predictable Relief

100 Tablets

Drug Facts

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- you need to use a laxative for more than 1 week

DRUG FACTS CONTINUED on back of the label ►

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by the owner of the registered trademark Dulcolax®

Distributed by: HHH Pharma USA LLC, Rahway, NJ 07065
www.hhhpharma.com

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PEEL HERE

LAXATIVE

bisacodyl tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83586-116
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

METHACRYLIC ACID (UNII: 1CS02G8656)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	B5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83586-116-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	07/28/2025	

Labeler - HHH PHARMA USA LLC (062788820)

Registrant - HHH PHARMA USA LLC (062788820)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		863182240	manufacture(83586-116)

Establishment

Name	Address	ID/FEI	Business Operations
HHH PHARMA USA LLC		062788820	pack(83586-116)