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	take 1 to 3 tablets in a
of age and over	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.

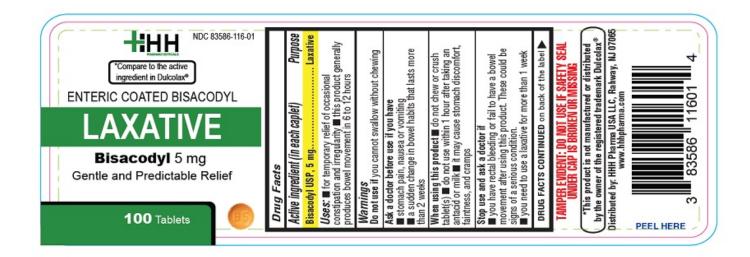
Questions or comments?

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. Directions ■ take with a glass of water Adults and children 12 take 1 to 3 tablets in a years of age and over single daily dose Children 6 to under 12 tablets once a day 12 years Children by ears ask a doctor	Other information store at controlled room temperature 20°-25°C (68°477°F). read all product information before use. Inactive ingredients: Colloidal silicon dioxide, hypromellose-5, magnesium stearate, matodextrin, methacrylic acid, microcrystalline cellulose, neelicert FD&C yellow 10 Al Lake, neelicert FD&C yellow 6Al Lake, PEG 400, sodium starch glycoslate, talc, titanium dioxide, triettryl citrate. Questions or comments? Call +1 848-235-5293 Monday through Friday 9AM – 4PM EST	
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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				

Ш	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:83586-116-	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)

Revised: 7/2025 HHH PHARMA USA LLC