LAXATIVE- bisacodyl tablet, delayed release
NORTHEAST PHARMA

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hpc 441

Active ingredient (in each tablet)

Bisacodyl 5 mg

Purpose

Stimulant Laxative

Uses

- for 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, vomiting
• noticed 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 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.

Directions

- take with a glass of water
- **do not take more than directed**

adults and children 12 years of age and over	1-3 tablets in a single daily dose
children 6 to under 12 years of age	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); excursions permitted between 15º-30ºC (59º-86ºF)
- avoid excessive humidity
- package not child resistant

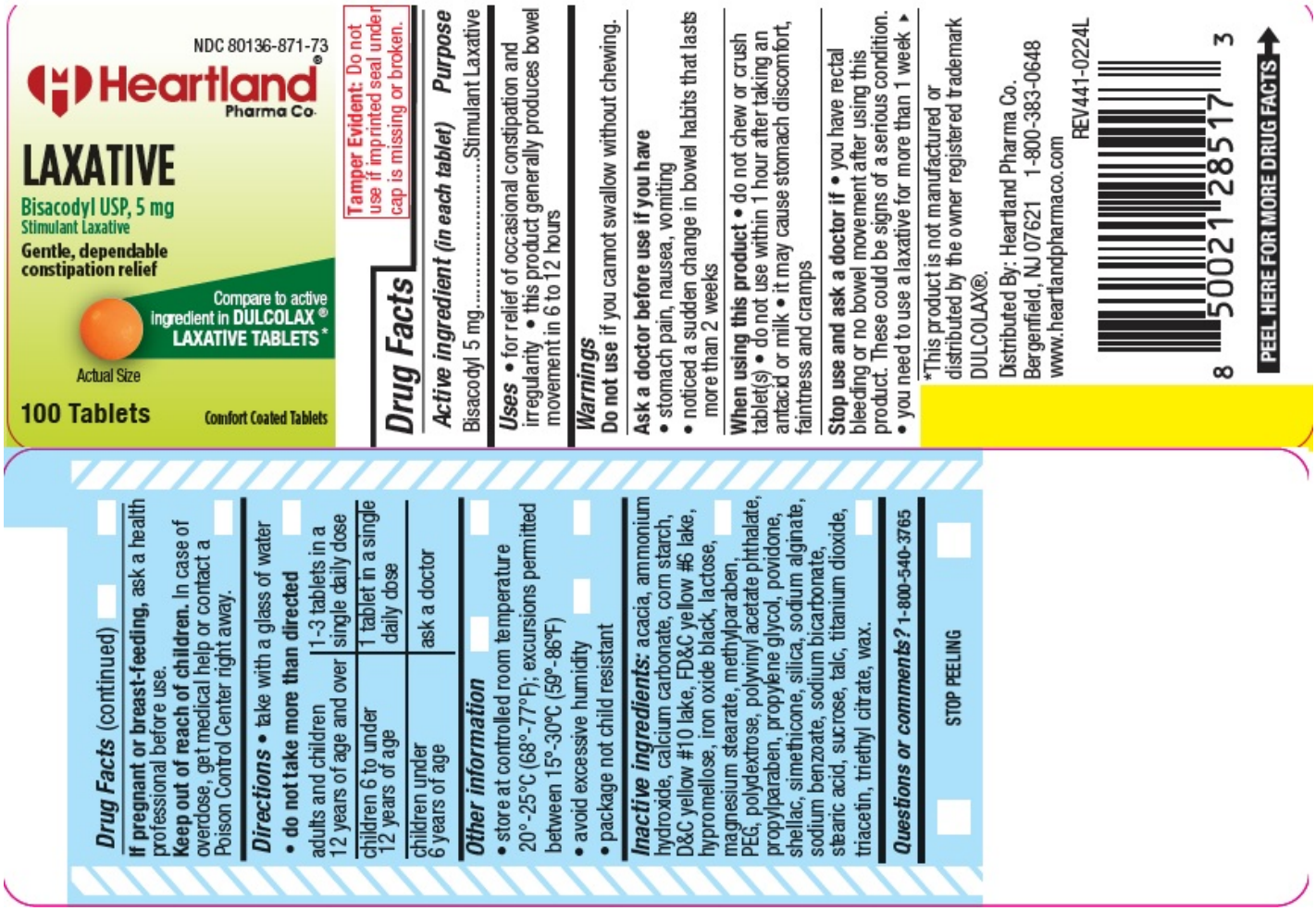
Inactive ingredients

acacia, ammonium hydroxide,
calcium carbonate, corn starch, D&C yellow #10 lake,
FD&C yellow #6 lake, hypromellose, iron oxide black, lactose,
magnesium stearate, methylparaben, PEG, polydextrose,
polyvinyl acetate phthalate, propylparaben, propylene glycol,
povidone, shellac, simethicone, silica, sodium alginate,
sodium benzoate, sodium bicarbonate, stearic acid, sucrose,
talc, titanium dioxide, triacetin, triethyl citrate, wax.

Questions or comments?

1-800-540-3765

Package Label



LAXATIVE

bisacodyl tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80136-871
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**
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ACACIA (UNII: 5C5403N26O)	
AMMONIA (UNII: 5138Q19F1X)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80136-871-73	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	02/01/2024	

Labeler - NORTHEAST PHARMA (081232935)

Registrant - Geri-Care Pharmaceutical Corp (611196254)