# BISACODYL LAXATIVE ENTERIC COATED- bisacodyl tablet, coated Good Sense (Geiss, Destin & Dunn, Inc.)

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 (in each tablet)

Bisacodyl USP 5 mg

## **Purpose**

Stimulant laxative

#### Use

- 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 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

adults and children 12 years of age and overtake 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 between 20°-25°C (68°-77°F)

#### **Inactive ingredients**

acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal silicon dioxide, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, iron oxide, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide

### Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

## **Principal Display Panel**

# Overnight Relief

Bisacodyl Laxative

Gentle, Predictable

Overnight Relief

Enteric Coated Tablets (5 mg Each)

\*Compare to active ingredient in Dulcolax®

# TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

\*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor of Dulcolax® Laxative.

Distributed by:

Geiss, Destin & Dunn, Inc.

Peachtree City, GA 30269 www.valuelabels.com Product of U.S.A.

#### **Product Label**



Monday-Friday 9AM-5PM EST

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Lot No.: Exp. Date:

professional before use. If pregnant or breast-feeding, ask a health

antacid or milk  If may cause stomach disco and cramps  Stop use and ask a doctor if myou have rectal bleeding or movement after using this p could be signs of a serious	en using this product o not chew or crush tablet(s) o not use within 1 hour after taking an ntacid or milk may cause stomach discomfort, faintness nd cramps		Inactive ingredients acacia, anhydrous calcium sulfate, anhydrous lactose, camauba calcium sulfate, anhydrous lactose, camauba wax, colloidal silicon dioxide, com starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, iron oxide, iron oxide, iron oxide, iron oxide, iron oxide, pelatin, magnesium stearate, microcrystalline cellulose, polyethylene glycol microcrystalline cellulose, polyethylene glycol cycol, polyvinyl acetate prithalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide	
Ask a doctor before use if yor stomach pain, nausea or vo a sudden change in bowel h	gnitimos	Other information a store between 20°-25°C (68°-77°F)		
Warnings Do not use if you cannot swal chewing.	sllow without	years of age children under 6 years of age	single daily dose ask a doctor	
	is broduct generally produces a bowel		e single daily dose s ni tablet 1 salst	
USE ■ for temporary relief of occas and irregularity	ssional constipation	Directions  Take with a glass of water  Take 1 to 3 tablets in		
Drug Facts Active ingredient (isldet Aaso ni) em 3 92U koosesia	<b>920qru</b> q evitexel Inslumit2	Drug Facts (continued)  Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.		

#### **Good Sense Laxative Tablets**

# **BISACODYL LAXATIVE ENTERIC COATED**

bisacodyl tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-190	
Route of Administration	ORAL			

# Active Ingredient/Active Moiety Ingredient Name BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y) BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y) BISACODYL 5 mg

Inactive Ingredients			
Ingredient Name	Strength		
<b>ACACIA</b> (UNII: 5C5403N26O)			
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)			
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STARCH, CORN (UNII: O8232NY3SJ)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SHELLAC (UNII: 46N107B710)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
SUCROSE (UNII: C151H8M554)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ 989GH94E)	

Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	6mm	
Flavor		Imprint Code	TCL003	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:50804- 190-03	1 in 1 CARTON	07/16/2010	01/31/2025		
1		25 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	07/16/2010	01/31/2025	

Labeler - Good Sense (Geiss, Destin & Dunn, Inc.) (076059836)

Revised: 10/2022 Good Sense (Geiss, Destin & Dunn, Inc.)