# BISACODY ENTERIC COATED- bisacodyl tablet, coated CVS Pharmacy

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.

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#### **DRUG FACTS**

#### Active ingredient (in each enteric coated 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)
- it may cause stomach discomfort, faintness or cramps
- do not use within 1 hour after taking an antacid or milk

#### 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 pregnancy 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

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 at controlled room temperature 15°-30°C (59°-86°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 (iron oxide ochre), magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polyvinyl acetate phthalate, povidone, shellac, sodium starch glycolate, stearic acid, sugar, talc, and titanium dioxide

#### Questions or comments?

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

#### **Principal Display Panel**

Compare to the active ingredient in DULCOLAX®\*

Gentle

#### **LAXATIVE**

#### **BISACODYL USP 5 mg**

- Guaranteed relief
- Gentle yet effective

Tablets

Enteric coated

## EACH TABLET IS INDIVIDUALLY SEALED IN A BLISTER PACK. DO NOT USE IF BLISTER FOIL IS BROKEN.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

#### OVERNIGHT RELIEF

\*This product is not manufactured or distributed by Boehringer Ingelheim Consumer Health Care Products, owner of the registered trademark Dulcolax®.

#### Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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www.cvs.com 1-800-shop-CVS

#### **Product Label**





# BISACODYL USP 5 mg

NDC 59779-990-03

Compare to the active ingredient in Dulcolax®

EACH TABLET IS INDIVIDUALLY SEALED IN A BLISTER PACK. Do not use if blister foil is broken.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

EXP. DATE: LOT NO.:

# BISACODYL USP 5 mg

- Guaranteed relief
- Gentle yet effective

25 Tablets **Enteric coated** 

Health Care Products, owner of the registered trademark Dulcolax®. This product is not manufactured or distributed by Boehringer Ingelheim Consumer

**Questions or comments?** Call toll tree 1-877-753-3935 Monday-Friday 9AM-5PM EST

sodium starch glycolate, stearic acid, sugar, talc, and titanium dioxide

Drug Facts (continued)

Inactive ingredients acacia, anhydrous calcium sulfate, anhydrous lactose, carnauba wax, colloidal sillicon dioxide, corn starch, D&C Yellow #10 Aluminum Lake, gelatin, iron oxide, iron oxide Black, iron oxide Vellow #6 Aluminum Lake, gelatin, iron oxide, iron oxide Black, iron oxide vollow #6 Aluminum Lake, gelatin, iron oxide, iron oxide ochre), magnesium stearate, microcrystalline cellulose, oxide ochre), magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polyvinyl acetate phithalate, povidone, shellac,

Under Intormation = store at controlled room temperature 15°-30°C (59°-86°F)

ask a doctor	children under 6 years of age
take 1 tablet in a single daily dose	children 6 to under 12 years of age
take 1 to 3 tablets in a single daily dose	adults and children 12 years of age and over
78	Directions take with a glass of water

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 Polson Control Center right away.

to use a laxative for more than 1 week Stop use and sak a doctor if wyou have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition. wyou need

When using this product ■ do not chew or crush tablet(s) ■ it may cause staking an antach discomfort, faintness and cramps ■ do not use within 1 hour after taking an antach or milk

Ask a doctor before use if you have a stomach pain, nauses or vomiting a sudden change in bowel habits that lasts more than 2 weeks

Do not use if you cannot swallow without chewing

Warnings

USe a for temporary relief of occasional constipation and irregularity after product generally produces a bowel movement in 6 to 12 hours

Bisacodyl, USP 5 mg. Purpose Active ingredient (in each enteric coated tablet)

Drug Facts

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
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#### **CVS GENTLE LAXATIVE**

#### **BISACODY ENTERIC COATED**

bisacodyl tablet, coated

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Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:59779-990

Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BISACODYL (BISACODYL)	BISACODYL	5 mg	

Inactive Ingredients				
Ingredient Name	Strength			
ACACIA				
CALCIUM SULFATE ANHYDRO US				
ANHYDROUS LACTOSE				
CARNAUBA WAX				
SILICON DIO XIDE				
STARCH, CORN				
D&C YELLOW NO. 10				
FD&C YELLOW NO. 6				
GELATIN				
MAGNESIUM STEARATE				
CELLULOSE, MICRO CRYSTALLINE				
SHELLAC				
SODIUM STARCH GLYCOLATE TYPE A POTATO				
STEARIC ACID				
TALC				
TITANIUM DIO XIDE				
Polyvinyl Acetate Phthalate				
SUCROSE				
POVIDONES				
FERRIC OXIDE RED				
FERRIC OXIDE YELLOW				
FERROSOFERRIC OXIDE				
POLYETHYLENE GLYCOL 400				
ALUMINUM O XIDE				

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

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:59779-990-03	1 in 1 CARTON				
1	25 in 1 BLISTER PACK				
2 NDC:59779-990-50	2 in 1 CARTON				
2	25 in 1 BLISTER PACK				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part334	0 1/10/20 13		

### Labeler - CVS Pharmacy (062312574)

**Registrant** - P and L Development of New York Corporation (800014821)

Revised: 3/2013 CVS Pharmacy