

**WOMENS GENTLE LAXATIVE- bisacodyl tablet, delayed release  
RETAIL BUSINESS SERVICES, LLC**

*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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**Women's Gentle Laxative**

***Drug Facts***

***Active Ingredient (in each softgel)***

Bisacodyl (USP) 5 mg

***Purpose***

Stimulant 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)
- it may cause stomach discomfort, faintness and 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 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 1(800)222-1222

## Directions

adults and children 12 years and over  
 children 6 to under 12 years of age  
 children under 6 years of age

1 to 3 tablets in a single daily dose  
 1 tablet in a single daily dose  
 ask a doctor

## Other Information

- store at 20-25°C (68-77°F)
- protect from excessive humidity

## Inactive ingredients

dextrose monohydrate, D&C Red #27, FD&C Blue #1, hypromellose, lactose monohydrate, lecithin, magnesium stearate, maltodextrin, methacrylic acid copolymer, methyl cellulose, pregelatinized starch, silica, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

## Questions or comments?

1-888-333-9792

## Principal Display Panel

Carton

<p><b>Drug Facts</b></p> <p><b>Active Ingredient (in each tablet)</b> Bisacodyl (USP) 5 mg.....Stimulant laxative</p> <p><b>Purpose</b> Stimulant laxative</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• for temporary relief of occasional constipation and irregularity</li> <li>• this product generally produces bowel movement in 6 to 12 hours</li> </ul> <p><b>Warnings</b></p> <p>Do not use if you cannot swallow without chewing</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> <li>• stomach pain, nausea or vomiting</li> <li>• a sudden change in bowel habits that lasts more than 2 weeks</li> </ul> <p>When using this product</p> <ul style="list-style-type: none"> <li>• do not chew or crush tablet(s)</li> <li>• it may cause stomach discomfort, faintness and cramps</li> <li>• do not use within 1 hour after taking an antacid or milk</li> </ul> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> <li>• you have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition.</li> <li>• you need to use a laxative for more than 1 week</li> </ul> <p>If pregnant or breast-feeding, ask a health professional before use.</p>		<p><b>Drug Facts (continued)</b></p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away: 1(800)222-1222</p> <p><b>Directions</b> • take with a glass of water</p> <table border="1"> <tr> <td>adults and children 12 years and over</td> <td>1 to 3 tablets in a single daily dose</td> </tr> <tr> <td>children 6 to under 12 years of age</td> <td>1 tablet in a single daily dose</td> </tr> <tr> <td>children under 6 years of age</td> <td>ask a doctor</td> </tr> </table> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>• each tablet contains: magnesium 5 mg</li> <li>• store at 20-25°C (68-77°F)</li> <li>• protect from excessive humidity</li> </ul> <p><b>Inactive ingredients</b>: dextrose monohydrate, D&amp;C Red #27, FD&amp;C Blue #1, hypromellose, lactose monohydrate, lecithin, magnesium stearate, maltodextrin, methacrylic acid copolymer, methyl cellulose, pregelatinized starch, silica, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate</p> <p><b>Questions or comments?</b> 1-888-333-9792</p>	adults and children 12 years and over	1 to 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
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<p><b>Women's Gentle Laxative</b> Bisacodyl USP 5 mg</p> <p>NDC 72476-960-25</p> <p>Compare to the active ingredient in Dulcolax® Pink® Laxative Tablets*</p> <p><b>Women's Gentle Laxative</b> Bisacodyl USP 5 mg</p> <ul style="list-style-type: none"> <li>• stimulant laxative</li> <li>• gentle, overnight relief</li> </ul> <p><b>25 tablets</b></p> <p>actual size</p> <p>LOT: EXP:</p>								

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTER UNIT IS INTACT

# WOMENS GENTLE LAXATIVE

bisacodyl tablet, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-960
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>AMMONIUM ACRYLOYL DIMETHYLTAURATE/METHACRYLATE, DIMETHYLACRYLAMIDE AND METHACRYLIC ACID COPOLYMER, PPG-3 GLYCERYL TRIACRYLATE CROSSLINKED (100000 MW)</b> (UNII: WR7H9IW2XX)	
<b>HYDROXYMETHYL CELLULOSE</b> (UNII: 273FM27VK1)	
<b>STARCH, POTATO</b> (UNII: 8I089SAH3T)	
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	F
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-960-25	1 in 1 CARTON	08/03/2022	

1	25 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/03/2022	

**Labeler** - RETAIL BUSINESS SERVICES, LLC (967989935)

Revised: 5/2023

RETAIL BUSINESS SERVICES, LLC