

**BET-R-PREP BISACODYL- bisacodyl tablet**  
**Satius Pharmaceuticals, 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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**BET-R-PREP Bisacodyl**

***Drug Facts***

**Active ingredient (in each tablet)**

Bisacodyl 5 mg

***Purpose***

Stimulant Laxative

***Uses***

- relieves occasional constipation and irregularity
- this product generally produces a bowel movement in 6 to 12 hours

***Warnings***

**Do not use**

- for more than one week unless directed by a doctor
- if you cannot swallow without chewing
- within 1 hour after taking an antacid or milk

**Ask a doctor before use if you have**

- abdominal pain
- nausea
- vomiting
- a sudden change in bowel habits that lasts longer than 2 weeks

**When using this product**

- abdominal discomfort, faintness, or cramps may occur

**Stop use and ask a doctor**

- if you have no bowel movement within 12 hours
- if you have rectal bleeding
- these could be signs of a serious condition

**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***

- do not take more than directed
- swallow whole, do not chew or crush
- take recommended dose in a single daily dose
- take with water
- adults and children 12 years and older: take 1-3 (usually 2) tablets daily
- children 12 and under: ask a doctor

**Other information**

- store at room temperature
- avoid excessive humidity

**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?**

contact us at:

732-430-2208

www.satiusrx.com

**Package Labeling:**

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

<p style="text-align: center; font-weight: bold;">TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING</p> <p style="text-align: center; font-weight: bold;">REV 441-1217</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"> <p><b>Drug Facts</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left; padding: 2px;">Active ingredient (in each tablet)</th> <th style="text-align: left; padding: 2px;">Purpose</th> </tr> <tr> <td style="padding: 2px;">Bisacodyl 5 mg.....</td> <td style="padding: 2px;">Stimulant Laxative</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ relieves occasional constipation and irregularity</li> <li>■ this product generally produces a bowel movement in 6 to 12 hours</li> </ul> <p><b>Warnings</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ for more than one week unless directed by a doctor</li> <li>■ if you cannot swallow without chewing</li> <li>■ within 1 hour after taking an antacid or milk</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ abdominal pain ■ nausea ■ vomiting</li> <li>■ a sudden change in bowel habits that lasts longer than 2 weeks</li> </ul> <p><b>When using this product</b> ■ abdominal discomfort, faintness, or cramps may occur</p> <p><b>Stop use and ask a doctor</b></p> <ul style="list-style-type: none"> <li>■ if you have no bowel movement within 12 hours</li> <li>■ if you have rectal bleeding</li> <li>■ these could be signs of a serious condition</li> </ul> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of</p> </td> <td style="width: 50%; padding: 5px;"> <p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ do not take more than directed</li> <li>■ swallow whole, do not chew or crush</li> <li>■ take recommended dose in a single daily dose</li> <li>■ take with water</li> <li>■ adults and children 12 years and older: take 1-3 (usually 2) tablets daily</li> <li>■ children 12 and under: ask a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ store at room temperature</li> <li>■ avoid excessive humidity</li> </ul> <p><b>Inactive ingredients:</b> acacia, ammonium hydroxide, calcium carbonate, corn starch, D&amp;C yellow #10 lake, FD&amp;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.</p> </td> </tr> <tr> <td colspan="2" style="padding: 5px;"> <p><b>Questions or comments?</b> contact us at: 732-430-2208</p> </td> </tr> </table>	<p><b>Drug Facts</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left; padding: 2px;">Active ingredient (in each tablet)</th> <th style="text-align: left; padding: 2px;">Purpose</th> </tr> <tr> <td style="padding: 2px;">Bisacodyl 5 mg.....</td> <td style="padding: 2px;">Stimulant Laxative</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ relieves occasional constipation and irregularity</li> <li>■ this product generally produces a bowel movement in 6 to 12 hours</li> </ul> <p><b>Warnings</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ for more than one week unless directed by a doctor</li> <li>■ if you cannot swallow without chewing</li> <li>■ within 1 hour after taking an antacid or milk</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ abdominal pain ■ nausea ■ vomiting</li> <li>■ a sudden change in bowel habits that lasts longer than 2 weeks</li> </ul> <p><b>When using this product</b> ■ abdominal discomfort, faintness, or cramps may occur</p> <p><b>Stop use and ask a doctor</b></p> <ul style="list-style-type: none"> <li>■ if you have no bowel movement within 12 hours</li> <li>■ if you have rectal bleeding</li> <li>■ these could be signs of a serious condition</li> </ul> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of</p>	Active ingredient (in each tablet)	Purpose	Bisacodyl 5 mg.....	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overdose, get medical help or contact a  
Poison Control Center right away.

1-822-430-2200  
www.satiusrx.com



Satius Pharmaceuticals  
1775 Highway 34  
Suite D-14  
Farmingdale, NJ 07727



Available from Physicians



25 TABLETS

STIMULANT LAXATIVE

**Bisacodyl** 5mg

ENTERIC COATED

**Bet-R-Prep**<sup>™</sup>

25 TABLETS 5 mg each

**Bisacodyl**

**Bet-R-Prep**<sup>™</sup>

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## BET-R-PREP BISACODYL

bisacodyl tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71890-330
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10 X0 709 Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

**Inactive Ingredients**

Ingredient Name	Strength
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	

**Product Characteristics**

Color	orange	Score	no score
Shape	ROUND	Size	1mm
Flavor		Imprint Code	5
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71890-330-25	1 in 1 BOX	11/18/2017	
1		25 in 1 PACKAGE; 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	11/18/2017	

**Labeler** - Satius Pharmaceuticals, LLC (080518631)

Revised: 10/2019

Satius Pharmaceuticals, LLC