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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Bisacodyl Enteric Coated Tablet

**Active ingredient(s)**
Bisacodyl 5mg

**Purpose**
Stimulant laxative

**Use(s)**
- relieves occasional constipation and irregularity
- this product generally produces bowel movement in 6 to 12 hours

**Warnings**

**Do not use**
Do not use if you cannot swallow without chewing

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

**When using this product**
- do not use within 1 hour after taking an antacid or milk
- do not chew or crush tablet(s)
- you may have stomach discomfort, faintness or cramps

**Stop use and ask a doctor if**
- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

**Pregnancy/Breastfeeding**
ask a health professions before use.

**Keep out of reach of children**
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 and over- take 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 at 25 degrees C (77 degrees F) excursions permitted between 15 degrees-30 degrees C (59 degrees-86 degrees F)
- use by expiration date on package
- protect from excessive humidity

Storage

Inactive ingredients
acacia, bees wax, calcium sulfate, carnauba wax, cellulose, corn starch, D&C Yellow No. 10 lake, FD&C Yellow No. 6 lake, gelatin, lactose, magnesium stearate, pharmaceutical glaze, polyvinyl acetate phthalate, silica gel, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide.

Questions
To Report Adverse Drug Event call: (800) 616-2471

Principal Display Panel
Bisacodyl Enteric Coated Tabs, USP 5mg
# MAJOR PHARMACEUTICALS

**NDC 0904-7927-61**  
Unit Dose  
**BISACODYL ENTERIC COATED TABLETS**  
(Delayed Release)  
5 mg.  
Stimulant Laxative  
100 TABLETS

## Drug Facts

<table>
<thead>
<tr>
<th>Active Ingredient (in each tablet)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisacodyl 5mg</td>
<td>Stimulant laxative</td>
</tr>
</tbody>
</table>

## Uses
- relieves 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 over 2 weeks
- When using this product:
  - do not chew or crush tablet
  - do not use within 1 hour after taking an antacid or milk
  - you may have stomach discomfort, faintness or cramps
- Stop use and ask a doctor if:
  - you have rectal bleeding or fail to have a bowel movement after use. These may be signs of a serious condition.
  - you need to use a laxative for more than 1 week
- If pregnant or breast-feeding, ask a doctor before use. Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

## Directions

<table>
<thead>
<tr>
<th>Adults and children 12 years and over</th>
<th>take 1 to 3 tablets (usually 2) in a single daily dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>children 6 to under 12 years</td>
<td>take 1 tablet daily</td>
</tr>
</tbody>
</table>
# BISACODYL ENTERIC COATED

bisacodyl tablet, coated

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:0904-7927</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of Administration</td>
<td></td>
<td>ORAL</td>
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## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
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<tbody>
<tr>
<td>BISACODYL</td>
<td>BISACODYL</td>
<td>5 mg</td>
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</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACACIA</td>
<td></td>
</tr>
<tr>
<td>CALCIUM SULFATE ANHYDROUS</td>
<td></td>
</tr>
<tr>
<td>ANHYDROUS LACTOSE</td>
<td></td>
</tr>
<tr>
<td>CARNAUBA WAX</td>
<td></td>
</tr>
<tr>
<td>SILICON DIOXIDE</td>
<td></td>
</tr>
<tr>
<td>STARCH, CORN</td>
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D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
FD&C YELLOW NO. 6 (UNII: H77VEB93A8)
GELATIN, UNSPECIFIED (UNII: 2GB6Q3N327L)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MICROCRYSTALLINE CELLULOSE (UNII: OPIR32D61U)
AMMONIUM NONOXYNOL-4 SULFATE (UNII: 9HIA70O4J0)
SHELLAC (UNII: 46N107B71O)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STEARIC ACID (UNII: 4ELV7Z65AP)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)

**Product Characteristics**

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<thead>
<tr>
<th>Color</th>
<th>Orange</th>
<th>Score</th>
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<tbody>
<tr>
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<td>Size</td>
<td>6mm (6mm)</td>
</tr>
<tr>
<td>Flavor</td>
<td></td>
<td>Imprint Code</td>
<td>5</td>
</tr>
<tr>
<td>Contains</td>
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**Packaging**

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<tr>
<th>#</th>
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<th>Marketing End Date</th>
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<tbody>
<tr>
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<td>NDC:0904-7927-17</td>
<td>25 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
<td>10/24/2008</td>
<td>07/31/2020</td>
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<td>2</td>
<td>NDC:0904-7927-60</td>
<td>100 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>10/24/2008</td>
<td>05/31/2021</td>
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<td>NDC:0904-7927-61</td>
<td>100 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product</td>
<td>10/24/2008</td>
<td>02/28/2018</td>
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<td>4</td>
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<td>1000 in 1 BOTTLE; Type 0: Not a Combination Product</td>
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<td>05/31/2021</td>
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**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>OTC monograph not final</td>
<td>part334</td>
<td>10/24/2008</td>
<td>05/31/2021</td>
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**Labeler** - Major Pharmaceuticals (191427277)

Revised: 10/2019