**DULCOLAX- bisacodyl tablet, coated**
**Boehringer Ingelheim Pharmaceuticals, 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.*

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**Dulcolax ®**
**Bisacodyl (USP) 5 mg Tablets/Stimulant Laxative**

***Drug Facts***

| ***Active ingredient (in each tablet)*** | ***Purpose*** |
|---|---|
| Bisacodyl (USP) 5 mg | Stimulant laxative |

***Use***
- 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**
- it may cause stomach discomfort, faintness and cramps
- do not chew or crush tablet(s)
- 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.

***Directions*** take with a glass of water

| | |
|---|---|
| adults and children 12 years of age 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 |

***Other information***
- store at 20-25°C (68-77°F

- protect from excessive humidity

***Inactive ingredients*** acacia gum, ammonium hydroxide, beeswax, carnauba wax, D&C Yellow #10 aluminum lake, D&C Red #30 aluminum lake, glycerin, glyceryl monostearate, iron oxide, lactose monohydrate, magnesium stearate, methacrylic acid ethyl acrylate copolymer, methyl paraben, modified corn starch, polyethylene glycol 6000, polysorbate 80, povidone, propyl paraben, shellac, sodium benzoate, sucrose, talc, titanium dioxide, triethyl citrate

***Questions?*** call **1-888-285-9159** (English/Spanish), M – F, 8:30 – 5 EST, or visit **www.Dulcolax.com**

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Dulcolax® 25 Tablets Carton

Dulcolax® 8 Tablets Carton


# DULCOLAX

bisacodyl tablet, coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0597-0012 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **BISACODYL** (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y) | BISACODYL | 5 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ACACIA** (UNII: 5C5403N26O) | |
| **AMMONIA** (UNII: 5138Q19F1X) | |
| **YELLOW WAX** (UNII: 2ZA36H0S2V) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **D&C RED NO. 30** (UNII: 2S42T2808B) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A** (UNII: NX76LV5T8J) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **POLYETHYLENE GLYCOL 6000** (UNII: 30IQX730WE) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | ORANGE | **Score** | no score |
| **Shape** | ROUND | **Size** | 5mm |
| **Flavor** | | **Imprint Code** | BI;12 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0597-0012-26 | 1 in 1 CARTON | 10/01/2001 | |
| **1** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:0597-0012-11 | 1 in 1 CARTON | 10/01/2001 | |
| **2** | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **3** | NDC:0597-0012-58 | 6 in 1 CARTON | 10/01/2001 | |
| **3** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **4** | NDC:0597-0012-59 | 8 in 1 CARTON | 10/01/2001 | |

| | | | | |
|---|---|---|---|---|
| **4** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **5** | NDC:0597-0012-50 | 2 in 1 CARTON | 10/01/2001 | |
| **5** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **6** | NDC:0597-0012-38 | 1 in 1 CARTON | 10/01/2001 | |
| **6** | | 8 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **7** | NDC:0597-0012-00 | 4 in 1 CARTON | 10/01/2001 | |
| **7** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **8** | NDC:0597-0012-37 | 2 in 1 CARTON | 10/01/2001 | |
| **8** | | 15 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 | 10/01/2001 | |

# DULCOLAX

bisacodyl tablet, coated

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0597-0340 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **BISACODYL** (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y) | BISACODYL | 5 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ACACIA** (UNII: 5C5403N26O) | |
| **AMMONIA** (UNII: 5138Q19F1X) | |
| **YELLOW WAX** (UNII: 2ZA36H0S2V) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE)** (UNII: 461P5CJN6T) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **D&C RED NO. 30** (UNII: 2S42T2808B) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A** (UNII: NX76LV5T8J) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **POLYETHYLENE GLYCOL 6000** (UNII: 30IQX730WE) | |

| | |
|---|---|
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | ORANGE | **Score** | no score |
| **Shape** | ROUND | **Size** | 5mm |
| **Flavor** | | **Imprint Code** | BI;12 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0597-0340-48 | 1 in 1 CARTON | 08/01/2013 | |
| **1** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:0597-0340-71 | 1 in 1 CARTON | 08/01/2013 | |
| **2** | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **3** | NDC:0597-0340-64 | 6 in 1 CARTON | 08/01/2013 | |
| **3** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **4** | NDC:0597-0340-97 | 8 in 1 CARTON | 08/01/2013 | |
| **4** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **5** | NDC:0597-0340-54 | 2 in 1 CARTON | 08/01/2013 | |
| **5** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **6** | NDC:0597-0340-82 | 1 in 1 CARTON | 08/01/2013 | |
| **6** | | 8 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **7** | NDC:0597-0340-70 | 4 in 1 CARTON | 08/01/2013 | |
| **7** | | 25 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **8** | NDC:0597-0340-72 | 2 in 1 CARTON | 08/01/2013 | |
| **8** | | 15 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 | 08/01/2013 | |

**Labeler -** Boehringer Ingelheim Pharmaceuticals, Inc. (603175944)

**Registrant -** Boehringer Ingelheim Pharmaceuticals, Inc. (603175944)

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Boehringer Ingelheim Pharmaceuticals, Inc.