

## **DULCOLAX - bisacodyl suppository**

**Physicians Total Care, 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® Suppository**

#### **Drug Facts**

| <b>Active ingredient (in each suppository)</b> | <b>Purpose</b>     |
|--|--------------------|
| Bisacodyl USP 10 mg .....                      | Stimulant laxative |

#### **Uses**

- for temporary relief of occasional constipation and irregularity
- this product generally produces bowel movement in 15 minutes to 1 hour

#### **Warnings**

For rectal use only

#### **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, rectal burning and mild cramps

#### **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.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

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adults and children 12 years of age and over 1 suppository in a single daily dose. Peel open plastic. Insert suppository well into rectum, pointed end first. Retain about 15 to 20 minutes.

children 6 to 12 years of age 1/2 suppository in a single daily dose

children under 2 years of age ask a doctor

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#### **Other information**

- do not store above 30°C (86°F)

**Inactive ingredient**

hydrogenated vegetable oil

Dulcolax (bisacodyl USP) Laxative Suppositories

10 mg

NDC 54868-3155-1

DIST. BY: PHYSICIANS TOTAL CARE  
 TULSA, OK 74146  
 NDC 54868-3155-1 16 SUP  
 DULCOLAX 10MG -OTC  
 LOT # 0000 EXP. DATE 01/60  
 MFG. BY: BIEHRINGER INGELHEIM, INC.  
 RIDGEFIELD CT 06077



**DULCOLAX**

bisacodyl suppository

**Product Information**

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:54868-3155(NDC:0597-0052) |
| <b>Route of Administration</b> | RECTAL         |                           |                               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| bisacodyl (UNII: 10X0709Y6I) (bisacodyl - UNII:10X0709Y6I) | bisacodyl         | 10 mg    |

**Inactive Ingredients**

| Ingredient Name                                 | Strength |
|---|----------|
| HYDROGENATED COCONUT OIL (UNII: JY810XM10M)     |          |
| HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP) |          |

**Product Characteristics**

|              |       |              |  |
|--------------|-------|--------------|--|
| <b>Color</b> | WHITE | <b>Score</b> |  |
|--------------|-------|--------------|--|

|                 |        |                     |  |
|-----------------|--------|---------------------|--|
| <b>Shape</b>    | BULLET | <b>Size</b>         |  |
| <b>Flavor</b>   |        | <b>Imprint Code</b> |  |
| <b>Contains</b> |        |                     |  |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:54868-3155-1 | 4 in 1 CARTON       |                      |                    |
| 1 |                  | 4 in 1 BLISTER PACK |                      |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334                                  | 03/17/2011           |                    |

**Labeler** - Physicians Total Care, Inc. (194123980)

### Establishment

| Name                        | Address | ID/FEI    | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Physicians Total Care, Inc. |         | 194123980 | relabel             |

Revised: 2/2011

Physicians Total Care, Inc.