

## **CVS GENTLE LAXATIVE- bisacodyl suppository suppository**

### **CVS Pharmacy**

*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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### **Active Ingredient (in each Suppository)**

#### **Purpose**

Bisacodyl USP, 10 mg.....Stimulant Laxative

### **Uses**

Uses - For relief of occasional constipation and irregularity

-This product generally produces bowel movement in 15 minutes to 1 hour

### **Warnings**

For rectal use only.

### **Do not use**

Do not use - more than once per day - for a period of longer than one week unless directed by a doctor - laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor

### **Ask a doctor**

Ask a doctor before use if you have - noticed a sudden change in bowel habits that persists over a period of two weeks

### **When using this product**

When using this product - May cause abdominal discomfort, faintness, rectal burning, and mild cramps

### **Stop use and ask a doctor**

Stop use and ask a doctor if you have rectal bleeding or fail to have bowel movement after using a laxative. This may indicate a serious condition

### **If pregnant or breast-feeding**

If pregnant or breast-feeding, ask a health professional before use.

### **Keep out of reach of children**

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

Adults and children 12 years of age and older

Children 6 to under 12 years

Children

under 6

One suppository once daily

1/2 suppository once daily

Ask doctor.

-Detach one suppository from the strip and remove from foil - Carefully insert one suppository well into the rectum

-Do not use more than once per day

### **Other information**

Other information - Store at room temperature: 15° - 30°C (59° - 86°F). Do not exceed 30°C (86°F) - Individually sealed for your protection. Do not use if foil is torn or open

### **Inactive ingredient**

Inactive ingredient Hydrogenated vegetable oil

### **Purpose**

Stimulant Laxative

### **Product Label**



## CVS GENTLE LAXATIVE

bisacodyl suppository suppository

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-107 |
| Route of Administration | RECTAL         |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength         |
|--|-------------------|------------------|
| BISACODYL (UNII: 10X0709Y6I) (BISACODYL - UNII:10X0709Y6I) | BISACODYL         | 10 mg in 2000 mg |

### Inactive Ingredients

| Ingredient Name                    | Strength           |
|------------------------------------|--------------------|
| PALM KERNEL OIL (UNII: B0S90M0233) | 1990 mg in 2000 mg |

| Product Characteristics |  |                         |                      |                    |
|-------------------------|--|-------------------------|----------------------|--------------------|
| Color                   | white                                    | Score                   |                      |                    |
| Shape                   | BULLET                                   | Size                    | 32mm                 |                    |
| Flavor                  |  | Imprint Code            |                      |                    |
| Contains                |  |                         |                      |                    |
|                         |  |                         |                      |                    |
| Packaging               |  |                         |                      |                    |
| #                       | Item Code                                | Package Description     | Marketing Start Date | Marketing End Date |
| 1                       | NDC:59779-107-17                         | 4 in 1 CARTON           | 09/18/2014           |                    |
| 1                       | NDC:59779-107-16                         | 40 mg in 1 BLISTER PACK |                      |                    |
|                         |  |                         |                      |                    |
| Marketing Information   |  |                         |                      |                    |
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date    | Marketing End Date   |                    |
| OTC monograph not final | part334                                  | 09/18/2014              |                      |                    |
|                         |  |                         |                      |                    |

**Labeler** - CVS Pharmacy (062312574)

| Establishment |         |           |                        |
|---------------|---------|-----------|------------------------|
| Name          | Address | ID/FEI    | Business Operations    |
| Unipack, Inc. |         | 009248480 | manufacture(59779-107) |