

DULCOLAX LAXATIVE- bisacodyl suppository
Chattem, Inc.

Dulcolax Medicated Laxative Suppository

Dulcolax®

Medicated Laxative Suppositories

Drug Facts

Active ingredient (*in each suppository*)

Bisacodyl (USP) 10 mg

Purpose

Stimulant laxative

Use

- for 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
- noticed 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 fail to have a 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

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

children 6 to under 12 years of age ½ suppository in a single daily dose

children under 6 years of age ask a doctor

Other information

- do not use if individual blister unit is open or torn
- store at 20°-25°C (68°-77°F)

Inactive ingredient

hard fat

Questions?

Call **1-866-844-2798** or visit **www.Dulcolax.com**

Keep carton as it contains important product information.

PRINCIPAL DISPLAY PANEL

Dulcolax
Bisacodyl (USP) 10 mg Suppository/ Stimulant Laxative
MEDICATED LAXATIVE SUPPOSITORY
4
COMFORT SHAPED
SUPPOSITORIES
DO NOT SWALLOW

**FAST RELIEF
WITHIN MINUTES**

Easy-to-insert, comfort shaped Dulcolax® Suppositories provide fast relief from constipation. Trust Dulcolax® Suppositories to work within 15 minutes to 1 hour when inserted rectally.

Tamper evident. Individually sealed for your protection.

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Distributed by:
Oxecta, Inc., a Shalick Company
P.O. Box 2719
Columbus, IN 47308-4279
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Dulcolax®

Bisacodyl (USP) 10 mg Suppository/Stimulant Laxative
MEDICATED LAXATIVE SUPPOSITORY



Gentle, predictable, fast relief

**FAST RELIEF
IN MINUTES**



4
COMFORT SHAPED
SUPPOSITORIES
DO NOT SWALLOW

*Among Stimulant Laxatives

Dulcolax® does not supply store brands.



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Questions? Call 1-866-844-2798
or visit www.Dulcolax.com

Drug Facts (continued)
Inactive ingredient hard fat

Other information • do not use if individual blister unit is open or torn
• store at 20°-25°C (68°-77°F)

Directions
adults and children 12 years of age and over
1 suppository in a single daily dose. Peel open plastic, insert suppository into rectum, pointed end first. Retain about 15 to 20 minutes.
children 6 to under 12 years of age
1/2 suppository in a single daily dose
ask a doctor
children under 6 years of age
ask a doctor

Warnings
For rectal use only
• stomach pain, nausea or vomiting
• record a sudden change in bowel habits that lasts more than 2 weeks
When using this product it may cause stomach discomfort, flatness, rectal burning and mild cramps
Stop use and ask a doctor if • you have rectal bleeding or fail to have a 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.

Use • for relief of occasional constipation and irregularly
Bisacodyl (USP) 10 mg
Stimulant laxative
• this product generally produces bowel movement in 15 minutes to 1 hour

Active ingredient (in each suppository)
Bisacodyl (USP) 10 mg
Stimulant laxative

Purpose

DULCOLAX LAXATIVE

bisacodyl suppository

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41167-0210 |
| Route of Administration | RECTAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------|-----------------|
| FAT, HARD (UNII: 8334LX7S21) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | white | Score | |
| Shape | BULLET | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:41167-0210-3 | 4 in 1 CARTON | 06/04/2019 | |
| 1 | | 4 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:41167-0210-5 | 7 in 1 CARTON | 06/04/2019 | |
| 2 | | 4 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:41167-0210-1 | 1 in 1 CARTON | 06/04/2019 | |
| 3 | | 4 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:41167-0210-2 | 2 in 1 CARTON | 06/04/2019 | |
| 4 | | 4 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 Drug | 505G(a)(3) | 06/04/2019 | |

