**LAXATIVE- bisacodyl tablet, delayed release**
**Advanced Rx LLC**

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### *Active ingredient (in each tablet)*

Bisacodyl USP, 5 mg

### *Purpose*

Stimulant laxative

### *Uses*

- for 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**

- do not chew or crush tablet(s)
- do not use within 1 hour after taking an antacid or milk
- it may cause stomach discomfort, faintness, and 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

**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*

- **do not take more than directed**

- 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 | take 1 tablet in a single daily dose |
| children under 6 years | ask a doctor |

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive humidity
- use by expiration date on package

***Inactive ingredients***

Colloidal silicon dioxide, Hypromellose-5, Magnesium stearate, Maltodextrin, Methacrylic acid, Microcrystalline cellulose, Neelicert FD&C Yellow 10 Al Lake, Neelicert FD&C Yellow 6 Al Lake, PEG 400, Purified Water, Sodium Starch Glycolate, Talc, Titanium Dioxide, Triethyl citrate.

***Questions or comments?***

**1-800-630-8895**

**Distributed by**

**ADVANCED RX LLC**

1942 NE 163rd St.North Miami Beach,

FL 33162 U.S.A.

**NDC 80513-409-20**

*Compare to Dulcolax ® Laxative Tablets Active Ingredient

**Laxative**

**Bisacodyl USP 5 mg**

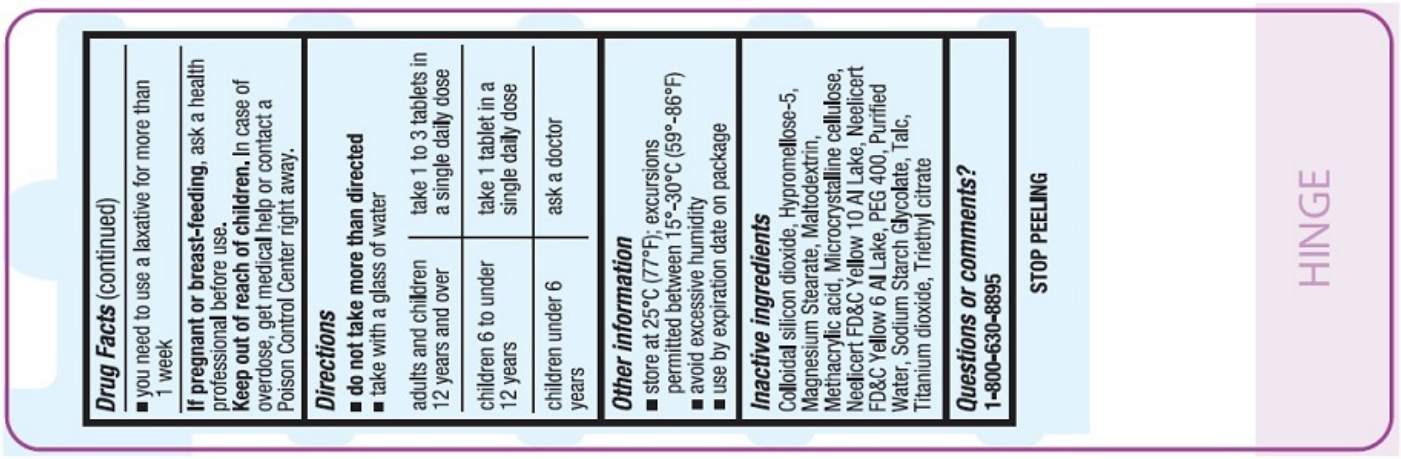
Gentle Predictable

Overnight Relief

200 Comfort Coated Tablets

*This product is not manufactured or distributed by the owner of the registered

trademark Dulcolax ®.


# LAXATIVE

bisacodyl tablet, delayed release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:80513-409 |
| **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** |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **HYPROMELLOSE 2910 (5 MPA.S)** (UNII: R75537T0T4) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |

| | |
|---|---|
| **METHACRYLIC ACID** (UNII: 1CS02G8656) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **D&C YELLOW NO. 10 ALUMINUM LAKE** (UNII: CQ3XH3DET6) | |
| **FD&C YELLOW NO. 6 ALUMINUM LAKE** (UNII: GYP6Z2JR6Q) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM STARCH GLYCOLATE TYPE A** (UNII: H8AV0SQX4D) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | orange | **Score** | no score |
| **Shape** | ROUND | **Size** | 6mm |
| **Flavor** | | **Imprint Code** | B5 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:80513-409-20 | 200 in 1 BOTTLE; Type 0: Not a Combination Product | 01/01/2025 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | 505G(a)(3) | 01/01/2025 | |

## Labeler - Advanced Rx LLC (042795108)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| ELYSIUM PHARMACEUTICALS LIMITED | | 915664486 | manufacture(80513-409) |

Revised: 1/2025 Advanced Rx LLC