# BISACODYL- bisacodyl tablet, delayed release Bryant Ranch Prepack

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Major 44-327

## 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	take 1 to 3 tablets in a single
years and over	daily dose
children 6 to under 12	take 1 tablet in a single daily
years	dose
children under 6 years	ask a doctor

#### Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive humidity
- see end flap for expiration date and lot number

## Inactive ingredients

acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac glaze, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

#### Questions or comments?

1-800-426-9391

#### **HOW SUPPLIED**

Bisacodyl USP, 5 mg

NDC: 71335-2010-0: 25 Tablets in a BOTTLE

NDC: 71335-2010-1: 30 Tablets in a BOTTLE

NDC: 71335-2010-2: 2 Tablets in a BOTTLE

NDC: 71335-2010-3: 3 Tablets in a BOTTLE

NDC: 71335-2010-4: 4 Tablets in a BOTTLE

NDC: 71335-2010-5: 10 Tablets in a BOTTLE

NDC: 71335-2010-6: 90 Tablets in a BOTTLE

NDC: 71335-2010-7: 8 Tablets in a BOTTLE

NDC: 71335-2010-8: 100 Tablets in a BOTTLE

NDC: 71335-2010-9: 20 Tablets in a BOTTLE

Repackaged/Relabeled by: Bryant Ranch Prepack, Inc.

Burbank, CA 91504

#### **Bisacodyl 5mg Tablet**



Each tablet contains: Bisacodyl, USP 5 mg.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° to 30° C (59° to 86° F) (see USP controlled Room Temperature).

Dispense in tight, light-resistant containers as defined in the USP.

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

NDC 71335-2010-1

Bisacodyl Tablets, USP

5 mg

PHARMACEUTICALS 30 Tablets

**Repackaged by:**Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
LNK International, Inc.



## **BISACODYL**

bisacodyl tablet, delayed release

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71335-2010(NDC:0904-6748)

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)		
CALCIUM CARBONATE (UNII: H0G9379FGK)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STARCH, CORN (UNII: 08232NY3SJ)		
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		

FERROSOFERRIC OXIDE (UNII: XM0M87F357)

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
SHELLAC (UNII: 46N107B710)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	5
Contains			

Pa	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335- 2010-0	25 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
2	NDC:71335- 2010-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
3	NDC:71335- 2010-2	2 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
4	NDC:71335- 2010-3	3 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
5	NDC:71335- 2010-4	4 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2022	
6	NDC:71335- 2010-5	10 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2022	
7	NDC:71335- 2010-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
8	NDC:71335- 2010-7	8 in 1 BOTTLE; Type 0: Not a Combination Product	01/12/2022	
9	NDC:71335- 2010-8	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	
10	NDC:71335- 2010-9	20 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	505G(a)(3)	12/01/2018		

## Labeler - Bryant Ranch Prepack (171714327)

## Registrant - Bryant Ranch Prepack (171714327)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bryant Ranch Prepack		171714327	REPACK(71335-2010), RELABEL(71335-2010)	

Revised: 4/2024 Bryant Ranch Prepack