BISACODYL- bisacodyl tablet, delayed release
Bryant Ranch Prepack

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.

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
- you may have 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

- 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

- 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

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?

(800)-616-2471

HOW SUPPLIED

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

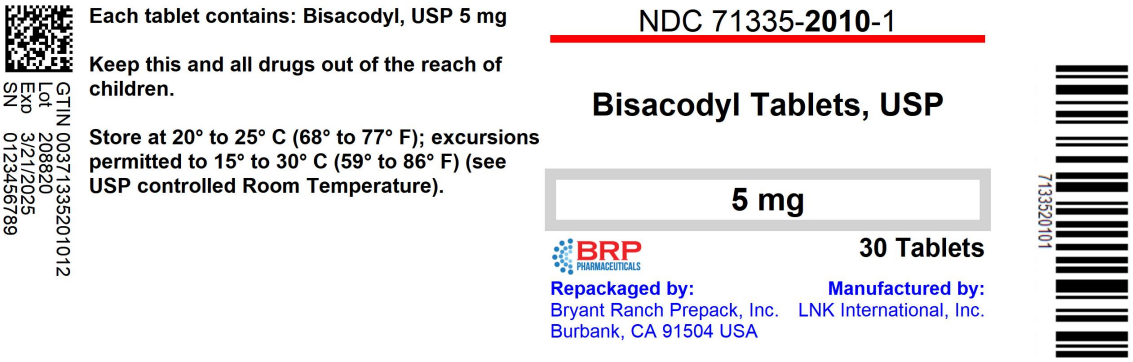
NDC: 71335-2010-6: 90 Tablets in a BOTTLE

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

Bisacodyl 5mg Tablet



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)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
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: 3WQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SHELLAC (UNII: 46N107B71O)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

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

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	02/24/2022	
2	NDC:71335-2010-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2022	
3	NDC:71335-2010-2	2 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2022	
4	NDC:71335-2010-3	3 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2022	
5	NDC:71335-2010-4	4 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2022	
6	NDC:71335-2010-5	10 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2022	
7	NDC:71335-2010-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2022	
8	NDC:71335-2010-7	8 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2022	
9	NDC:71335-2010-8	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2022	
10	NDC:71335-2010-9	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	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: 3/2023 Bryant Ranch Prepack