ENTERIC COATED ASPIRIN REGULAR STRENGTH- aspirin tablet, delayed release

Bryant Ranch Prepack

331R Timely 49483-331 Aspirin 325mg Delayed Release Tablets

DRUG FACTS

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID*) *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

temporarily relieves minor aches and pains due to:

- headache
- muscle pain
- toothache
- menstrual pain
- colds
- minor arthritis pain

or as recommended by a doctor

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

• if you are allergic to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

• taking a prescription drug for diabetes, gout, or arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:

feel faint

have bloody or black stools

vomit blood

have stomach pain that does not get better

- pain gets worse or lasts more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 to 2 tablets every 4 hours while symptoms last. Do not take more than 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

Other information

- each tablet contains: sodium 1 mg (VERY LOW SODIUM)
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients corn starch, croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions or comments? call 1-877-290-4008

HOW SUPPLIED

NDC: 71335-0157-1: 30 Tablets in a BOTTLE

NDC: 71335-0157-2: 60 Tablets in a BOTTLE

NDC: 71335-0157-3: 100 Tablets in a BOTTLE

NDC: 71335-0157-4: 90 Tablets in a BOTTLE

NDC: 71335-0157-5: 20 Tablets in a BOTTLE

NDC: 71335-0157-6: 45 Tablets in a BOTTLE

NDC: 71335-0157-7: 120 Tablets in a BOTTLE

NDC: 71335-0157-8: 7 Tablets in a BOTTLE

Aspirin E.C 325mg Tablet



ENTERIC COATED ASPIRIN REGULAR STRENGTH

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71335-0157(NDC:49483-331)
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	AS PIRIN	325 mg		

Inactive Ingredients		
	Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)		

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)

D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

MINERAL OIL (UNII: T5L8T28FGP)

POLYSORBATE 80 (UNII: 6OZ P39Z G8H)

DIMETHICONE (UNII: 92RU3N3Y1O)

SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	Т
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335- 0157-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
2	NDC:71335- 0157-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
3	NDC:71335- 0157-3	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/19/2018	
4	NDC:71335- 0157-4	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
5	NDC:71335- 0157-5	20 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
6	NDC:71335- 0157-6	45 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
7	NDC:71335- 0157-7	120 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
8	NDC:71335- 0157-8	7 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/04/2011	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bryant Ranch Prepack		171714327	REPACK(71335-0157), RELABEL(71335-0157)	

Revised: 1/2024 Bryant Ranch Prepack