# LOW DOSE ASPIRIN- aspirin tablet, coated Bryant Ranch Prepack

-----

#### 481R-TCL-49483-481 ASPIRIN 81MG DELAYED RELEASE TABLETS

#### **DRUG FACTS**

# Active ingredient (in each tablet)

Aspirin 81 mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

# **Purpose**

Pain reliever

#### Uses

for the temporary relief of minor aches and pains or as recommended by your doctor **Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.**ask your doctor about other uses for enteric-coated 81 mg Aspirin

## 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
- if you have ever had an allergic reaction to this product or any of its ingredients

#### 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
- 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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

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 overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

#### OTHER INFORMATION

#### Other information

- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients** anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

#### Questions? Call 1-877-290-4008

#### **HOW SUPPLIED**

NDC: 71335-1382-8: 15 Tablets in a BOTTLE

NDC: 71335-1382-1: 120 Tablets in a BOTTLE

NDC: 71335-1382-2: 30 Tablets in a BOTTLE

NDC: 71335-1382-3: 100 Tablets in a BOTTLE

NDC: 71335-1382-4: 20 Tablets in a BOTTLE

NDC: 71335-1382-5: 90 Tablets in a BOTTLE

NDC: 71335-1382-6: 60 Tablets in a BOTTLE

NDC: 71335-1382-7: 36 Tablets in a BOTTLE

NDC: 71335-1382-9: 10 Tablets in a BOTTLE

Repackaged/Relabeled by: Bryant Ranch Prepack, Inc. Burbank, CA 91504

### Aspirin 81 mg EC Tablet



Each tablet contains: Aspirin, 81 mg.

Keep this and all drugs out of the reach of children.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Take with food.

**NDC** 71335-**1382**-1

Aspirin USP

81 mg

BRP

Repackaged by: Bryant Ranch Prepack, Inc. Burbank, CA 91504 USA 120 Tablets

Manufactured by:
Time Cap

Laboratories Inc.



# **LOW DOSE ASPIRIN**

aspirin tablet, coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71335-1382(NDC:49483-481)

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients	
Ingredient Name	Strength
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	

Product Characteristics			
Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	HEART
Contains			

Packaging			
Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:71335- 1382-8	15 in 1 BOTTLE; Type 0: Not a Combination Product	01/06/2021	
NDC:71335- 1382-1	120 in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2021	
NDC:71335- 1382-2	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2020	
NDC:71335- 1382-3	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2021	
NDC:71335- 1382-4	20 in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	
NDC:71335- 1382-5	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/15/2021	
NDC:71335- 1382-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2022	
NDC:71335- 1382-7	36 in 1 BOTTLE; Type 0: Not a Combination Product	12/31/2020	
NDC:71335- 1382-9	10 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2022	
	NDC:71335- 1382-8 NDC:71335- 1382-1 NDC:71335- 1382-2 NDC:71335- 1382-3 NDC:71335- 1382-4 NDC:71335- 1382-5 NDC:71335- 1382-6 NDC:71335- 1382-7 NDC:71335-	NDC:71335- 15 in 1 BOTTLE; Type 0: Not a Combination Product  NDC:71335- 120 in 1 BOTTLE; Type 0: Not a Combination Product  NDC:71335- 30 in 1 BOTTLE; Type 0: Not a Combination Product  NDC:71335- 182-2  NDC:71335- 100 in 1 BOTTLE; Type 0: Not a Combination Product  NDC:71335- 20 in 1 BOTTLE; Type 0: Not a Combination Product  NDC:71335- 182-4  NDC:71335- 90 in 1 BOTTLE; Type 0: Not a Combination Product  NDC:71335- 182-5  NDC:71335- 182-6  NDC:71335- 1382-6  NDC:71335- 1382-7  NDC:71335- 10 in 1 BOTTLE; Type 0: Not a Combination Product  NDC:71335- 10 in 1 BOTTLE; Type 0: Not a Combination Product  NDC:71335- 10 in 1 BOTTLE; Type 0: Not a Combination Product  NDC:71335- 10 in 1 BOTTLE; Type 0: Not a Combination	Item Code         Package Description         Marketing Start Date           NDC:71335- 1382-8         15 in 1 BOTTLE; Type 0: Not a Combination Product         01/06/2021           NDC:71335- 1382-1         120 in 1 BOTTLE; Type 0: Not a Combination Product         01/04/2021           NDC:71335- 1382-2         30 in 1 BOTTLE; Type 0: Not a Combination Product         03/12/2020           NDC:71335- 1382-3         100 in 1 BOTTLE; Type 0: Not a Combination Product         01/21/2021           NDC:71335- 1382-4         20 in 1 BOTTLE; Type 0: Not a Combination Product         12/18/2020           NDC:71335- 1382-5         90 in 1 BOTTLE; Type 0: Not a Combination Product         03/15/2021           NDC:71335- 1382-6         60 in 1 BOTTLE; Type 0: Not a Combination Product         03/10/2022           NDC:71335- 1382-7         36 in 1 BOTTLE; Type 0: Not a Combination Product         12/31/2020           NDC:71335- 1382-7         10 in 1 BOTTLE; Type 0: Not a Combination Product         03/10/2022

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	06/19/2015		
OTC Monograph Drug	M013	06/19/2015		

# Labeler - Bryant Ranch Prepack (171714327)

# Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-1382), RELABEL(71335-1382)

Revised: 5/2024 Bryant Ranch Prepack