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

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#### 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

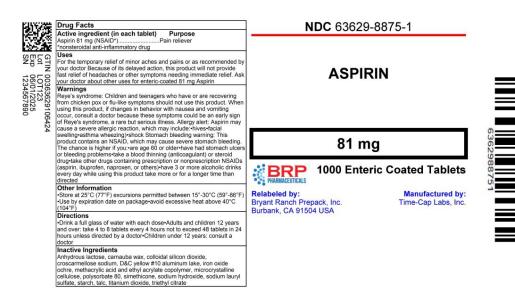
### Questions? Call 1-877-290-4008

#### **HOW SUPPLIED**

NDC: 63629-8875-1: 1000 Tablets in a BOTTLE, PLASTIC

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

# Aspirin 81 mg Tablet #1000



# **LOW DOSE ASPIRIN**

aspirin tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63629-8875(NDC:49483-481)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	AS PIRIN	81 mg		

Inactive Ingredients				
Ingredient Name	Strength			
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				

SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)

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

BROWN IRON OXIDE (UNII: 1N032N7MFO)

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

POLYSORBATE 80 (UNII: 60ZP39Z G8H)

DIMETHICONE (UNII: 92RU3N3Y1O)

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

STARCH, CORN (UNII: 08232NY3SJ)

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				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:63629- 8875-1	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
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(63629-8875), RELABEL(63629-8875)	

Revised: 1/2024 Bryant Ranch Prepack