# IBUPROFEN- ibuprofen tablet, film coated Bryant Ranch Prepack

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GC 941

## Active ingredient (in each brown tablet)

Ibuprofen USP, 200 mg (NSAID)\*
\*nonsteroidal anti-inflammatory drug

## **Purpose**

Pain reliever/fever reducer

#### Uses

- Temporarily relieves minor aches and pains due to:
- headache
- toothache
- backache
- menstrual cramps
- the common cold
- muscular aches
- minor pain of arthritis
- Temporarily reduces fever

## **Warnings**

**Allergy Alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- shock
- hives
- facial swelling
- asthma (wheezing)
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

## 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
   Heart attack and stroke warning: NSAIDs, except aspirin, increase
   the risk of heart attack, heart failure, and stroke. These can be
   fatal. The risk is higher if you use more than directed or for
   longer than directed.

#### Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

#### Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma
- you are taking a diuretic

### Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

## When using this product

take with food or milk if stomach upset occurs

## Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding: -feel faint -vomit blood -have bloody or black stools -have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain trouble breathing leg swelling
  - slurred speech weakness in one part or side of body
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- fever gets worse or lasts more than 3 days
- any new symptoms occur

## If pregnant or breast-feeding,

ask a health professional before use. it is especially important not to use ibuprofen 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 (1-800-222-1222) right away.

#### **Directions**

- do not use more than directed
- the smallest effective dose should be used
- adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not take more than 6 tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

#### Other information

- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)

## Inactive ingredients

carnauba wax, colloidal silicon dioxide, cellulose, corn starch, hypromellose, lactose, magnesium stearate, polydextrose, PEG, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide.

#### **Questions or comments?**

Call 1-800-540-3765

#### **HOW SUPPLIED**

NDC: 63629-1467-1: 20 Tablets in a BOTTLE

NDC: 63629-1467-2: 15 Tablets in a BOTTLE

NDC: 63629-1467-3: 30 Tablets in a BOTTLE

NDC: 63629-1467-4: 100 Tablets in a BOTTLE

NDC: 63629-1467-5: 60 Tablets in a BOTTLE

NDC: 63629-1467-6: 50 Tablets in a BOTTLE

NDC: 63629-1467-7: 40 Tablets in a BOTTLE

NDC: 63629-1467-8: 10 Tablets in a BOTTLE

NDC: 63629-1467-9: 56 Tablets in a BOTTLE

NDC: 63629-1467-0: 90 Tablets in a BOTTLE

Repackaged/Relabeled by:

Bryant Ranch Prepack, Inc.

Burbank, CA 91504

Ibuprofen 200mg Tablet



Each tablet contains: Ibuprofen, USP 200 mg

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

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).

Take with food.

#### NDC 63629-1467-1

#### **Ibuprofen Tablets**

200 mg

BRP

20 Tablets

Repackaged by: Bryant Ranch Prepack, Inc. Burbank, CA 91504 USA Manufactured by: Geri Care Pharmaceuticals Corp



## **IBUPROFEN**

ibuprofen tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63629-1467(NDC:57896-941)

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10QM)

BUPROFEN (UNII: WK2XYI10QM) | BUPROFEN | 200 mg

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYDEXTROSE (UNII: VH2XOU12IE)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44291

## Contains

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629- 1467-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2005	
2	NDC:63629- 1467-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2017	
3	NDC:63629- 1467-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2005	
4	NDC:63629- 1467-4	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2006	
5	NDC:63629- 1467-5	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2006	
6	NDC:63629- 1467-6	50 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2009	
7	NDC:63629- 1467-7	40 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2008	
8	NDC:63629- 1467-8	10 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2010	
9	NDC:63629- 1467-9	56 in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2010	
10	NDC:63629- 1467-0	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/20/2013	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA075010	01/01/2004	

## Labeler - Bryant Ranch Prepack (171714327)

## Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-1467), RELABEL(63629-1467)

Revised: 10/2023 Bryant Ranch Prepack