IBUPROFEN (NSAID) PAIN RELEIVER/ FEVER REDUCER- ibuprofen tablet Amneal Pharmaceuticals of New York LLC

Ibuprofen Caplets, USP Fever reducer/ Pain Reliever (NSAID)

Drug Facts

Active ingredient (in each caplet)

Ibuprofen USP, 200 mg (NSAID)**

**nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

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

- hives
- facial swelling
- asthma(wheezing)
- shock
- 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 ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- the 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, kidney disease, asthma, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- 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
- weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in 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

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 take more than directed
- the smallest effective dose should be used

Adults and children 12 years and older	 take 1 caplet every 4 to 6 hours while symptoms persist if pain or fever does not respond to 1 caplet, 2 caplets may be used do not exceed 6 caplets in 24 hours, unless directed by a doctor
Children under 12 years	ask a doctor

Other information

- read all warnings and directions before use
- store between 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

- Brown Caplets: Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Corn Starch, Hypromellose, Iron Oxide Red, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide
- Orange Caplets: Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Corn Starch, FD&C Yellow #6, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide

Questions or Comments?

Call 1-877-835-5472

Monday through Friday 9AM - 5PM EST.

*Amneal Pharmaceuticals is not affiliated with the owner of the trademark Advil®

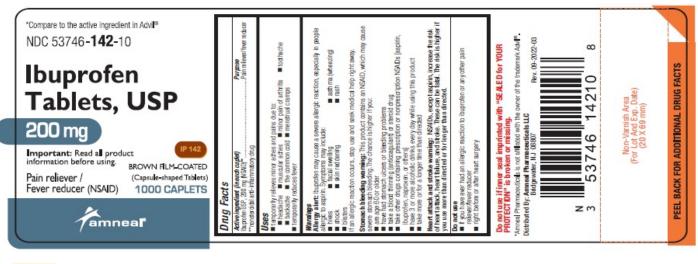
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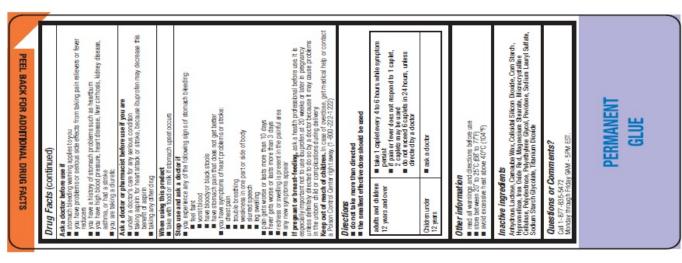
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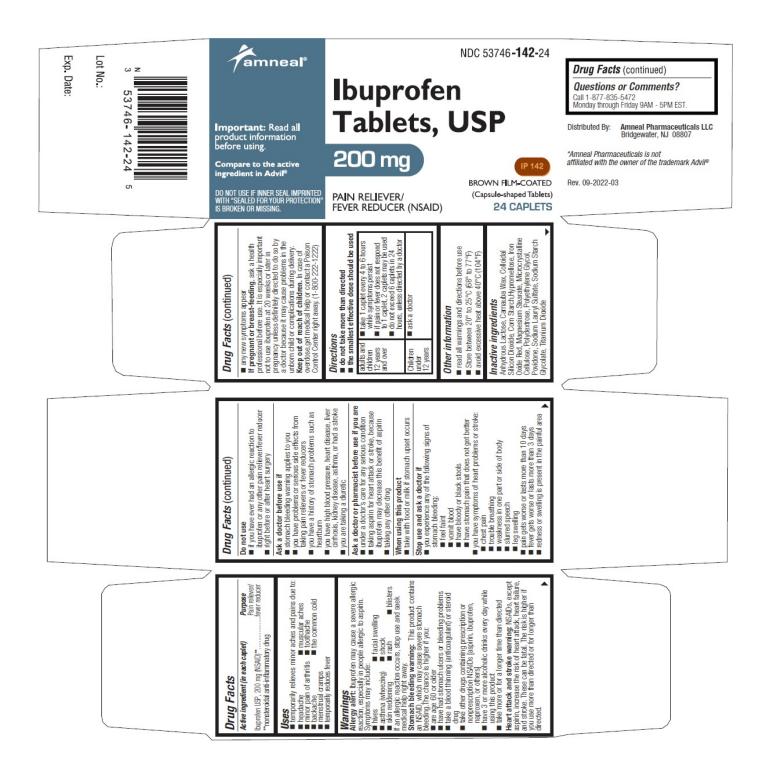
Bridgewater, NJ 08807

Rev. 09-2022-02

PACKAGE LABEL PRINCIPAL DISPLAY PANEL







PACKAGE LABEL PRINCIPAL DISPLAY PANEL

*Compare to the active ingredient in Motrin IB®

NDC 53746-144-10

Ibuprofen Tablets, USP

200 mg

Important: Read all product information before using.

Pain reliever / Fever reducer (NSAID)



ORANGE FILM-COATED (Capsule-shaped Tablets) 1000 CAPLETS

blakers an allergic reaction occurs, stop use and seek medical high right away.

If you have ever had an allergic reaction to ibuprofen or any other pain releven flavor reducer right before or after heart surgery Do not use if inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

Pev. 09-2022-03 Ostributed By: Amneal Pharmaceuticals LLC Bridgewater, NJ 08307

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PEEL BACK FOR ADDITIONAL DRUG FACTS

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Drug Facts (continued)

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■ skin reddening
■ sash

If pregnant or breast-leading, ask a health profesoloral before use, it is especially important for bea disputed by the control of their pregnancy unless especially important for the sell-quented at 20 weeks of their pregnancy unless of caching viacuate to do so by a coordinatese it may cause problems in the unborn dutil or complications during delivery. Assept and of reach of dufferent in case of coedings, get medical help or contact. Assept and a Polason Control Center of the sell-asseption of 1300-2223 (2022) and 2022).

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Children under 12 years

Other information

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adults and children 12 years and over

Heart attack and stroke warning. NSNDs, except aspirin, increase the risk of heart attack, heart fature, and stroke. These can be fatal. The risk is higher rocu use more than directed or for longer than directed.

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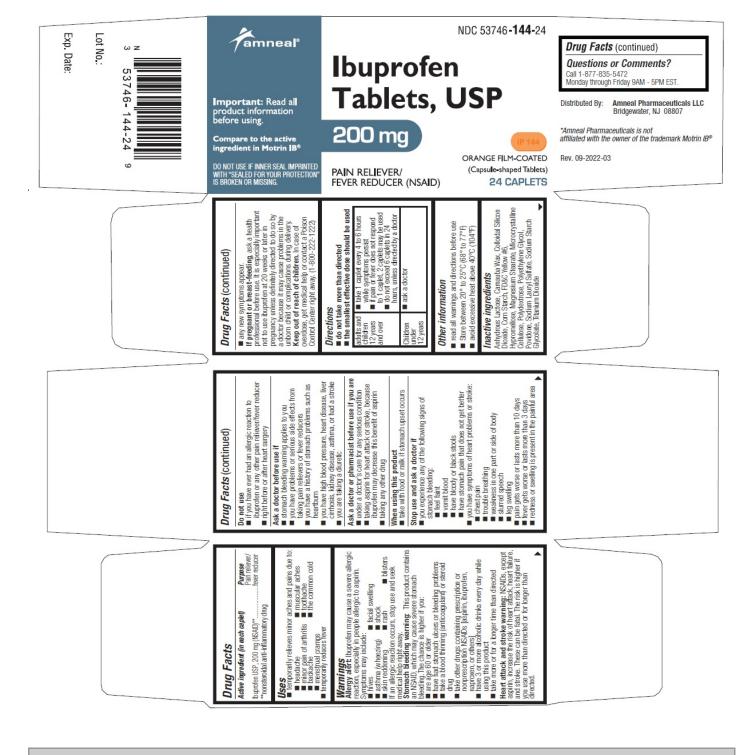
Artydous Lactoe, CansubaWax, Codolda Stron Dioride, Com Starch, FD&C Birtw & Hydromatica Agenesian Microsystaline Callutes. Polytex rose Poletrheire (Igos), Podone, Sodium Larryl Sultae, Sodium Sarari Syociae, Trafium Diocie

Call 1-877-835-5472 Monday through Friday 9AM - 5PM EST.

Questions or Comments?

Non-Varnish Area (For Lot And Exp. Date) (20 X 69 mm)

PERMANENT



IBUPROFEN (NSAID) PAIN RELEIVER/ FEVER REDUCER

ibuprofen tablet

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53746-144		
Route of Administration	ORAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POLYDEXTROSE (UNII: VH2XOU12IE)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE (UNII: FZ 989GH94E)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
STARCH, CORN (UNII: O8232NY3SJ)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics					
Color orange Score no score					
Shape	CAPSULE	Size	14mm		
Flavor		Imprint Code	IP;144		
Contains					

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:53746-144- 24	24 in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2009		
2	NDC:53746-144- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2009		
3	NDC:53746-144- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2009		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
ANDA	ANDA072199	12/16/2009		

IBUPROFEN (NSAID) PAIN RELEIVER/ FEVER REDUCER

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53746-142
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg		

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POLYDEXTROSE (UNII: VH2XOU12IE)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE (UNII: FZ 989GH94E)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
STARCH, CORN (UNII: O8232NY3SJ)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics				
Color brown Score no score				
Shape	CAPSULE	Size	14mm	
Flavor		Imprint Code	IP;142	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:53746-142- 24	24 in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2009		
2	NDC:53746-142- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2009		
3	NDC:53746-142- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2009		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072199	12/16/2009	

Labeler - Amneal Pharmaceuticals of New York LLC (123797875)

Revised: 12/2023 Amneal Pharmaceuticals of New York LLC