IBUPROFEN- ibuprofen tablet Amneal Pharmaceuticals of New York LLC

Ibuprofen Tablets USP, 200 mg Pain reliever/fever reducer (NSAID)

Drug Facts

Active ingredient

(in each 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
 - 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 right away. (1-800-222-1222)

Directions

- do not take 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 exceed 6 tablets 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 Tablets: colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide red, magnesium stearate, maltodextrin, microcrystalline cellulose, polydextrose, pregelatinized starch, stearic acid, talc, titanium dioxide, triglycerides

Orange Tablets: colloidal silicon dioxide, croscarmellose sodium, FD&C Yellow #6,

hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polydextrose, pregelatinized starch, stearic acid, talc, titanium dioxide, triglycerides

White Tablets: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or Comments?

Call 1-877-835-5472

Monday through Friday 9AM - 5PM EST.

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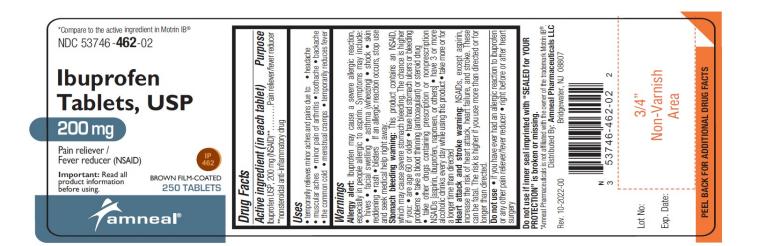
Amneal Pharmaceuticals LLC

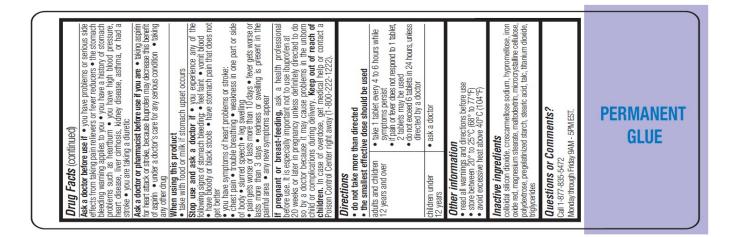
Bridgewater, NJ 08807 Rev. 10-2022-00

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

NDC 53746-462-02 Ibuprofen Tablets USP, 200 mg 250 Tablets

Amneal Pharmaceuticals LLC





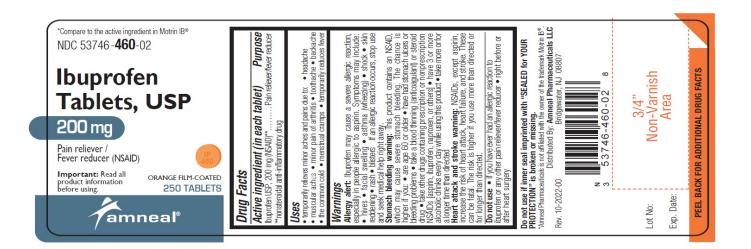
PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

NDC 53746-460-02

Ibuprofen Tablets USP, 200 mg

250 Tablets

Amneal Pharmaceuticals LLC



Drug Facts Continued) Are adoctor before use if • you have problems or serious side freets from taking pain releases or their endocers of the structures of the struct
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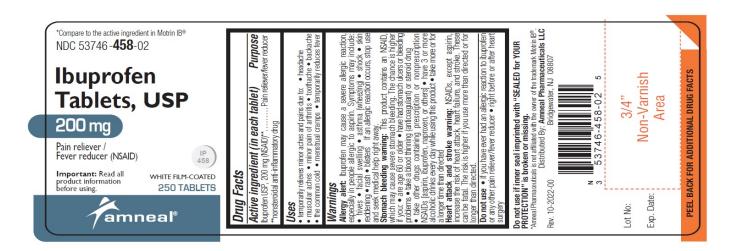
PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

NDC 53746-458-02

Ibuprofen Tablets USP, 200 mg

250 Tablets

Amneal Pharmaceuticals LLC



Drug Facts (continued) ask a doctor before use if • you have problems or serious side effects from taking pain ellevers or fever reducers • the stormach beeing warming applies to you • you have high blood pressure. Intern disease, liver cirritosis, kidney disease, asthma, or had a stoke • you are taking a diuretc. A actor or pharmacist before use if you are - twing asprin for keat data or stoke, becase buroten may decrease this bentil or hear ductor or pharmacist before use if you are - twing asprin for keat data or stoke, becase buroten may decrease this bentil or hear ductor or pharmacist before use if you are - twing asprin for hear ductor or pharmacist before use if you are - twing asprin and mark doctor scare for any serious condition • taking	When using this product: The unit of this product if even state with food or milk if somech upsering any of the relevant product yes and ask a doctor if even state any of the relevant product and the state of the state someth pain that does not get behave symptoms of heart problems or strokes. • you have symptoms of heart problems or strokes • you have symptoms of heart problems or strokes. • you have symptoms of heart problems or strokes. • or such a stroke something • weakness in one part or side of boy • surred speech • legs swifting • pain gets worse or tasks more than 10 days • lever gets worse or the pregnant or breast-feeding, ask a health professional before use. It is especially important not to use hupforen at 20 by a doctor because it may cause problems in the unbom children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).	Directions • oo not take more than directed • oo not take more than directed • the smallest effective does period to burs while • fitpan or the take more than directed • fitpan or the take more than directed • fitpan or the take more than the take does not respond to 1 tablet • fitpan or the does not respond to 1 tablet • fitpan or tables may be used • donot exceed 6 tablets in 24 hours, unless • directed by a doctor 12 years • and directions before use • store between 20° to 25°C (69° b) 77°F) • avoid excessive heat above 40°C (104°F)	Inactive ingredients colloidal silicon dioxide, croscarmellose sodum, magnesium stearate, microcrystalline cellulose, polyeithylene glycol, polyvinyl alcolol, pricrocrystalline cellulose, polyeithylene glycol, polyvinyl alcolol, microcrystalline cellulose, polyeithylene glycol, polyvinyl alcolol, pricrocrystalline cellulose, polyeithylene glycol, polyvinyl alcolol, coll 1-877-835-5472 Monday trough Fidey 9AM - 5PM EST.	PERMANENT GLUE
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IBUPROFEN					
buprofen tablet					
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (Source)	NDC:53	746-462
Route of Administration	ORAL				
A . 11 . I It 1/A . 11 .					
Active Ingredient/Active	Molety				
Ingre	dient Name		Basis of Stre	ngth	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10	QM)	IBUPROFEN		200 mg
Inactivo Ingradiante					
Inactive Ingredients					
	Ingredient Name			5	Strength

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	IP;462
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53746-462- 02	250 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2013	
2	NDC:53746-462- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2013	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
ANDA	ANDA079233	04/30/2013	

IBUPROFEN ibuprofen tablet					
Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (Source)	NDC:53	746-460
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingred	lient Name		Basis of Stre	ngth	Strength
IBUPROFEN (UNII: WK2XYI10QM) (I	BUPROFEN - UNII:WK2XYI10	QM)	IBUPROFEN		200 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
STARCH, CORN (UNII: 08232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	IP;462
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:53746-460- 02	250 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2013	
2	NDC:53746-460- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2013	

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateANDAANDA07923304/30/201304/30/2013

IBUPROFEN ibuprofen tablet				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53746-458	
Route of Administration	ORAL			

A	ctive Ingredi	ent/Act	ive Moiety					
		Ing	gredient Name	•	Basis of St	rength	Strength	
IBUPROFEN (UNII: WK2XYI100			M) (IBUPROFEN - U	INII:WK2XYI10QM)	IBUPROFEN		200 mg	
Ir	active Ingre	dients						
	J		Ingredie	ent Name			Strength	
sı	LICON DIOXIDE	(UNII: ETJ7Z	Z6XBU4)					
СІ	ROSCARMELLOS	E SODIUM	I (UNII: M28OL1HH4	18)				
M	AGNESIUM STEA	RATE (UNI	I: 70097M6I30)					
СІ	ELLULOSE, MICR	OCRYSTA	LLINE (UNII: OP1R	32D61U)				
PC	DLYETHYLENE G	LYCOL, UN	NSPECIFIED (UNII:	3WJQ0SDW1A)				
	TARCH, CORN (U							
S٦	EARIC ACID (UN	II: 4ELV7Z6	55AP)					
T/	ALC (UNII: 7SEV7]	4R1U)						
тι		E (UNII: 15F	FIX9V2JP)					
PC	DLYVINYL ALCOP	IOL, UNSP	PECIFIED (UNII: 53	2B59J990)				
Ρ	roduct Chara	acteristi	ics					
Color			brown	Score		no score		
Shape		ROUND	Size		9mm			
Flavor				Imprint Code		IP;462		
С	ontains							
P	ackaging							
#	ltem Code		Package Des	cription	Marketing Start Date	Mark	eting End Date	
1	NDC:53746-458- 02	250 in 1 B Product	SOTTLE; Type 0: No	ot a Combination	04/30/2013			
2	NDC:53746-458- 10	1000 in 1 Product	BOTTLE; Type 0: N	lot a Combination	04/30/2013			
Μ	larketing	Inform	nation					
	Marketing Category	Арр	lication Numbe Citati	r or Monograph	Marketing Start Date	Mar	keting End Date	
	category		Citati	011	Date		Date	
AN	IDA	ANDA07		on	04/30/2013		Date	

Labeler - Amneal Pharmaceuticals of New York LLC (123797875)

Revised: 12/2023

Amneal Pharmaceuticals of New York LLC