IBUPROFEN (NSAID) PAIN RELEIVER/FEVER REDUCER- ibuprofen tablet Amneal Pharmaceuticals

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

INDICATIONS AND USAGE

- 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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chances are 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 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

- 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, or kidney disease
- you have asthma
- 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
- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug

When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

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
- 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 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

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.

DOSAGE AND ADMINISTRATION

- 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 ● ask a doctor 12 years

OTHER INFORMATION

- Store between 20 25°C (68 77°F)
- Read all warnings and directions before use

INACTIVE INGREDIENTS

Brown Caplets: Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Hypromellose, Iron Oxide Red, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Corn Starch Corn, Titanium Dioxide

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

Questions or Comments

Call 1-877-835-5472

Monday through Friday 9AM - 5PM EST.

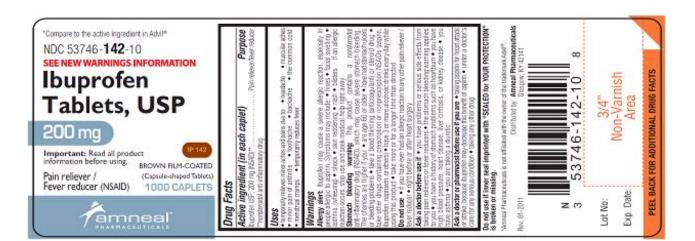
*Amneal Pharmaceuticals is not affiliated with the owner of the trademark Advil®

Distributed By:

Ameal Pharmaceuticals

Glasgow, KY 42141

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



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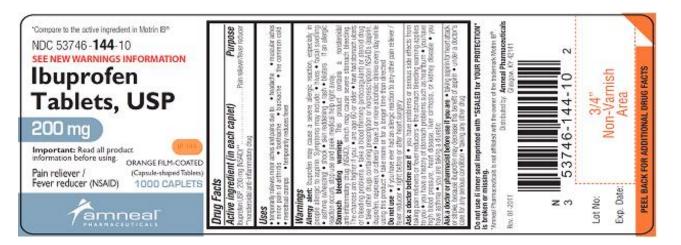
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aday through Friday 9AM + 5PM EST

Questions or Comments?

CM11-677-835-5472

PERMANENT GLUE



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Read all warnings and Carnaube Way, Colloidal Silicon Digide, Com Standt using this product • (3kg with food or milk if stomech upset) risk of fleath effeck of stroke may increase if you use dart not to use toprates warmy care because definities directed to do so by a doctor because in the untern chief or complications during definery. do not take more fran directed the smallest offective dose should be used Other Information Store between 20° to 25°C (68° to 77°F) PERMANENT Monday through Friday 940M - SPM EST. · ask a doctor **GLUE Ovestions or Comments?** out of reach of children. In 1939 nactive Ingredients MIT-877-826-6472 ithen under NDC 53746-142-24 amneal Lot No.: Exp. Date: **SEE NEW WARNINGS INFORMATION** Drug Facts (continued) ωZ **Ibuprofen** Questions or Comments? 53746-142-24 Call 1-877-835-5472 Monday through Friday 9AM - 5PM EST Tablets, USP Distributed by: **Amneal Pharmaceuticals** Glasgow, KY 42141 Important: Read all product information *Amneal Pharmaceuticals is not affiliated with the owner of the trademark Advil®. 200 mg Rev. 01-2011 BROWN FILM-COATED 5 (Capsule-shaped Tablets) PAIN RELIEVER/ FEVER REDUCER (NSAID) 24 CAPLETS If pregnant or breast-feetling, ask a health professional before use; it is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitiely 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 (1-800-222-1222). if pain of 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 Magnesium Stearate, Microcystalline Cellulose, Polydextrose, Polydethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide Anhydrous Lactose, Carnauba Wax, Colloidal Silicor Dioxide, Corn Starch, Hypromellose, Iron Oxide Red ■ Store between 20° to 25°C (68° to 77°F) ■ Read all warnings and directions before use ■ take 1 caplet every 4 to 6 hours while symptoms persist the smallest effective dose should be used Directions ■ do not take more than directed **Drug Facts** (continued) ask a doctor Inactive ingredients Other information Adults and children 12 years and older Children you have problems or senious side effects from taking again releves to refeer feducers. It is stomach bleeding warning applies to you have a history of stomach problems such as hearthurn blood pressure, heart disease, liver rinness, or kidney disease. I you have high blood pressure, heart disease, liver rinness, or kidney disease. you have settima. have bloddy or black stools have stomach pain that does not get better pain gets worse or elsts more than 10 days if ever gets worse or lasts more than 3 days if ever gets worse or lasts more than 3 days if ever gets worse or lasts more than 3 days if ever gets worse or lasts more than 3 days 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 When using this product take with food or milk if stomach upset occurs the risk of heart attack or stroke may increase if you use more than directed or for longer ■ if you have ever had an allergic reaction to any other pain reliever / fever reducer ■ right before or after heart surgery Drug Facts (continued) any new symptoms appea Ask a doctor before use if taking any other drug vomit blood Do not use If an allergic reaction occurs, stop use and seek medical help right away. Stomach bleeding warning. This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause sever stomach bleeding. The chances are higher if you. ■ are age 60 or older. ■ have had stomach ulcers or bleeding problems. ■ take a blood thinning (anticoagulant) or steroid. Pain reliever/ fever reducer temporarily relieves minor aches and pains due to: a 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 blisters toothachethe common cold muscular aches Allergy alert: Ibuprofen may cause a severe ctive ingredient (in each caplet) Ibuprofen USP, 200 mg (NSAID)**. minor pain of arthritisbackache menstrual cramps temporarily reduces fever

Drug Facts

headache

Exp. Date: Lot No.:

ωz

amneal

SEE NEW WARNINGS INFORMATION

Ibuprofen Tablets, USP

200 mg

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

ask a doctor

under 12 years Children

take 1 caplet every 4 to 6 hours

Adults and

do not take more than directedthe smallest effective dose should be used

ORANGE FILM-COATED PAIN RELIEVER/ (Capsule-shaped Tablets) FEVER REDUCER (NSAID) 24 CAPLETS

Read all warnings and directions before use

nactive ingredients

Store between 20° to 25°C (68° to 77°F)

Other information

Drug Facts (continued)

Questions or Comments? Call 1-877-835-5472 Monday through Friday 9AM - 5PM EST.

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Amneal Pharmaceuticals Glasgow, KY 42141

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Rev. 01-2011



Important: Read all product information before using.

Compare to the active ingredient in Motrin IB[®]

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

Drug Facts (continued)

the common cold

temporarily reduces fever menstrual cramps

Warnings
Allergy alert: Ibuprofen may cause a severe
allergic reaction, especially in people allergic to
aspirin. Symptoms may include: hivesasthma (wheezing)skin reddening

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

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chances are 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

Lake other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofer, naproven, or others)

There is none alcoholic drinks every day while using this product

Lake more or for a feature.

Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Corn Starch, FD&C Yellow #6, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Powidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide

NDC 53746-144-24

Drug Facts (continued)

Purpose Pain reliever/ fever reducer

Drug Facts

if you have ever had an allergic reaction to any other pain reliever / fever reducer right before or after heart surgery Do not use

you have problems or serious side effects from taking pain relievers or fever reducers
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, or kidney disease
you have asthma
you have asthma

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 When using this product
= take with rood or milk if stomach upset occurs
= the risk of heart attack or stroke may increase
if you use more than directed or for longer under a doctor's care for any serious condition taking any other drug

Stop use and ask a doctor if

you experience any of the following signs of stomach bleeding:

Feel faint

wornful blood

wornful blood

wornful blood

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temporarily relieves minor aches and pains due to:

The headache muscular aches toothache facial swellingshockrash Active ingredient (in each caplet) Ibuprofen USP, 200 mg (NSAID)**.....*
**nonsteroidal anti-inflammatory drug minor pain of arthritis

IBUPROFEN (NSAID) PAIN RELEIVER/ FEVER REDUCER

ibuprofen tablet

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS LACTOSE (UNII: 3S Y5LH9 PMK)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYDEXTROSE (UNII: VH2XOU12IE)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH9 4E)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		
STARCH, CORN (UNII: O8232NY3SJ)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

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			
2	NDC:53746-144-01	100 in 1 BOTTLE			
3	NDC:53746-144-10	1000 in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End 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		
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg		

Inactive Ingredients				
Ingredient Name	Strength			
ANHYDRO US LACTO SE (UNII: 3S Y5L H9 PMK)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
HYPROMELLOSES (UNII: 3NXW29 V3WO)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
PO VIDO NE (UNII: FZ989 GH9 4E)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STARCH, CORN (UNII: O8232NY3SJ)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

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			
2	NDC:53746-142-01	100 in 1 BOTTLE			
3	NDC:53746-142-10	1000 in 1 BOTTLE			

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

Labeler - Amneal Pharmaceuticals (123797875)

Establishment				
Name	Address	ID/FEI	Business Operations	
Amneal Pharmaceuticals		831227801	ANALYSIS, MANUFACTURE, LABEL, PACK	

Revised: 2/2012 Amneal Pharmaceuticals