

IBUPROFEN (NSAID) PAIN RELIEVER/ 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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®

Distributed By:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

Rev. 09-2022-02

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

*Compare to the active ingredient in Advil®
NDC 53746-142-10

Ibuprofen Tablets, USP

200 mg

Important: Read all product information before using.

Pain reliever / Fever reducer (NSAID)

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

Drug Facts

Active ingredient (strength 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
 - muscle aches
 - backache
 - the common cold
 - minor pain of arthritis
 - menstrual cramps
 - toothache
- temporarily reduces fever

Warnings:

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

- skin rash
- hives
- wheezing
- asthma (wheezing)
- rash

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

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinner (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 the 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

Do not use if inner seal imprinted with "SEAL FOR YOUR PROTECTION" is broken or missing.

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

PEEL BACK FOR ADDITIONAL DRUG FACTS

Drug Facts (continued)

Asks doctor before use if:

- you are bleeding warning tablets 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, asthma, or had a stroke
- you are taking a diuretic

Asks 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 the 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
 - 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 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)

Directions:

- do not take more than directed
- the smallest effective dose should be used

adults and children 12 years and over	<ul style="list-style-type: none"> ■ take 1 caplet every 4 to 6 hours while symptom persists ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor
Child 6 to 11 years	<ul style="list-style-type: none"> ■ 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

Artydross Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Corn Starch, Hypromellose, Iron Oxide (Red), Magnesium Stearate, Microcrystalline Cellulose, Polybutadiene, Polyethylene Glycol, Povidone K, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide

Questions or Comments?

Call 1-877-435-5472
Monday through Friday 9AM - 5PM EST.

PERMANENT
GLUE

PEEL BACK FOR ADDITIONAL DRUG FACTS

Exp. Date:

Lot No.:



amneal[®]

Important: Read all product information before using.

Compare to the active ingredient in Advil[®]

DO NOT USE IF INNER SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

NDC 53746-142-24

Ibuprofen Tablets, USP

200 mg

PAIN RELIEVER/
FEVER REDUCER (NSAID)

IP 142

BROWN FILM-COATED
(Capsule-shaped Tablets)
24 CAPLETS

Drug Facts (continued)

Questions or Comments?

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

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Bridgewater, NJ 08807

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Rev. 09-2022-03

Drug Facts (continued)

- any new symptoms appear
- 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.** In case of overdose, get medical help or contact Poison Control Center right away. (1-800-222-1222)

Directions

- do not take more than directed**
- the smallest effective dose should be used**
- 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 and over
- do not exceed 6 caplets in 24 hours, unless directed by a doctor
- 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

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

Drug Facts (continued)

- 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**
- 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 arthritis, kidney disease, asthma, or had a stroke
 - 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
- do not drink any of the following signs of stomach bleeding:
- red or black stools
- blood in vomit
- 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

Drug Facts

Active ingredient (in each caplet)

Purpose
Pain reliever/
fever reducer

Ibuprofen USP, 200 mg (NSAID)^{**}.....fever reducer
^{**}nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - headache
 - menstrual cramps
 - backaches
 - the common cold
- temporarily reduces fever

Warnings

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

- hives
- skin redness
- asthma (wheezing)
- facial swelling
- rash
- blisters

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

Stomach bleeding warning: This product contains NSAIDs. Stomach ulcers and 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.

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.

ORANGE FILM-COATED

Pain reliever /
Fever reducer (NSAID)

(Capsule-shaped Tablets)
1000 CAPLETS



IP 144

PEEL BACK FOR ADDITIONAL DRUG FACTS

Drug Facts (continued)

Ask a doctor before use if

- 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 disease, kidney disease, asthma, or had a stroke
- you are taking a利尿剂

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 its benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- you experience any of the following signs of stomach bleeding:
- heart burn
- vomit blood
- black stools
- low stomach pain that does not get better

Stop use and ask a doctor if

- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling

- joint pain or legs more than 10 days
- swelling of feet or legs 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. In case of overdosage, 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	<ul style="list-style-type: none"> 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°)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

Hydrous Lactose, Carnauba Wax, Coloidal Silicon Dioxide, Corn Starch, FD&C Yellow #6, Hydroxytoluene, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol 400, Polyethylene Glycol 600, Polyethylene Glycol 800, Polyethylene Glycol 1500, Polyethylene Glycol 2000, Polyethylene Glycol 4000, Polyethylene Glycol 6000, Polyethylene Glycol 8000, Polyethylene Glycol 10000, Polyethylene Glycol 15000, Polyethylene Glycol 20000, Polyethylene Glycol 40000, Polyethylene Glycol 60000, Polyethylene Glycol 80000, Polyethylene Glycol 100000, Polyethylene Glycol 150000, Polyethylene Glycol 200000, Polyethylene Glycol 400000, Polyethylene Glycol 600000, Polyethylene Glycol 800000, Polyethylene Glycol 1000000

Questions or Comments?

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

**PERMANENT
GLUE**

Drug Facts

Active ingredient (in each caplet): Ibuprofen (NSAID)
Purpose: Pain reliever/fever reducer
Contains: Aspirin, salicylic acid, and inflammatory drug

Uses

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

Warnings

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

- hives
- facial swelling
- stomach
- skin redness
- itching
- asthma (wheezing)
- rash

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, etc.)
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, even at aspirin, increase the risk of heart attack, heart failure, and stroke. These risks are 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

Do not use if inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

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Bridgewater, NJ 08807



Rev. 09-2022-03
Non-Varnish Area
(For Lot And Exp. Date)
(20 X 69 mm)

PEEL BACK FOR ADDITIONAL DRUG FACTS

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
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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: FZ989GH94E)	
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			

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

IBUPROFEN (NSAID) PAIN RELIEVER/ 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: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3S5YLH9PMK)	
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: FZ989GH94E)	
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			

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