

IBUPROFEN PAIN RELIEVER/FEVER REDUCER- ibuprofen capsule, liquid filled **Amneal Pharmaceuticals LLC**

Ibuprofen Capsules **(liquid filled, 200 mg)**

OTC - ACTIVE INGREDIENT

(in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*

(present as the free acid and potassium salt)

* nonsteroidal anti-inflammatory drug

OTC - PURPOSE

Pain reliever/Fever reducer

INDICATIONS AND USAGE

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:

- 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.

OTC - DO NOT USE

Do not use

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

OTC - ASK DOCTOR

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 cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

OTC - ASK DOCTOR/PHARMACIST

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

OTC - WHEN USING

When using this product

- take with food or milk if stomach upset occurs

OTC - STOP USE

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

OTC - PREGNANCY OR BREAST FEEDING

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.

OTC - 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.

DOSAGE AND ADMINISTRATION

Directions

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

OTHER INFORMATION

- each capsule contains: **potassium 20 mg**
- read all warnings and directions before use. Keep carton.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

INACTIVE INGREDIENT

FD&C Blue # 1, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitol

OTC - QUESTIONS OR COMMENTS?

Call 1-877-835-5472

Monday through Friday 9AM - 5PM EST.

Read and keep carton for complete warnings and information.

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

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

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

Rev. 06-2022-02

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65162-356-02

Ibuprofen Capsules, 200 mg

20 Capsules

Amneal Pharmaceuticals LLC

*Compare to the active ingredient in Advil® LIQUI-GELS®
NDC 65162-356-02
SEE NEW WARNINGS INFORMATION
Ibuprofen Capsules
200 mg
Pain reliever / Fever reducer (NSAID)
A356
Important: Read all product information before using.
SOFT GELATIN CAPSULES**
** (Liquid Filled Capsules)
20 Capsules
amneal

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts
Active ingredient (in each capsule) Purpose
Solubilized ibuprofen equal to Pain reliever/
200 mg ibuprofen (NSAD)* Fever reducer
(present as the free acid and potassium salt)
*nonsteroidal anti-inflammatory drug

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

Do not use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.
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Bridgewater, NJ 08807
Rev. 06-2022-02

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Lot No:
Exp. Date:

Non-Varnish Area

(continued)

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Drug Facts (continued)

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

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

Other information

- each capsule contains: **potassium 20 mg**
- read all warnings and directions before use. Keep carton.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

FD&C Blue # 1, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitol

Questions or Comments?

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

Drug Facts (continued)

- 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

- 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
 - 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.

Drug Facts (

Warnings

Allergy alert Ibuprofen may cause severe allergic reactions in people who are allergic to aspirin. Symptoms include:

- hives
- asthma (wheezing)
- shock
- rash
- swelling of the face, lips, tongue, or throat

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

Stomach bleeding

Ibuprofen may cause stomach bleeding. This risk is higher if you:

- are age 60 or older
- have had stomach problems
- take a blood thinner or steroid drug
- take other drugs, such as aspirin, or nonprescription drugs like ibuprofen, naproxen
- have 3 or more alcohol drinks a day while using this product
- take more or for a longer time than directed

Heart attack and stroke

Ibuprofen, except aspirin, may increase the risk of heart attack, heart failure, and stroke. The risk can be fatal. The risk is higher if you have had heart disease, high blood pressure, or are taking other drugs that affect the heart.

Do not use

- if you have ever had a heart attack or stroke
- right before or after heart surgery

Ask a doctor before

- stomach bleeding
- you have problems with your stomach or intestines
- you have a history of heartburn

Exp. Date:

Lot No:

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SEE NEW WARNINGS INFORMATION

NDC 65162-356-02

Ibuprofen Capsules

200 mg

A356

SOFT GELATIN CAPSULES**
** (Liquid Filled Capsules)

Pain reliever /
Fever reducer (NSAID)

20 Capsules

Important: Read all product information before using.

*Compare to the active ingredient in Advil® LIQUI-GELS®

DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

Drug Facts (continued)

Questions or Comments?

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Drug Facts (continued)

- 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

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

- each capsule contains: **potassium 20 mg**
- read all warnings and directions before use.
- keep carton.
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Inactive ingredients

FD&C Blue # 1, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitol

Drug Facts (continued)

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

- 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, 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

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

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredient (in each capsule)

Sulfated ibuprofen (equal to 200 mg ibuprofen (NSAID)*, Fever reducer (present as the free acid and potassium salt) *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- backache
- the common cold
- minor pain or arthritis
- 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
- skin reddening
- shock
- asthma (wheezing)
- 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

IBUPROFEN PAIN RELIEVER/FEVER REDUCER

ibuprofen capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65162-356

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
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Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	A356
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-356-02	1 in 1 CARTON	03/29/2013	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:65162-356-69	1 in 1 CARTON	03/29/2013	
2		80 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:65162-356-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2013	
4	NDC:65162-356-11	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202300	03/29/2013	

Labeler - Amneal Pharmaceuticals LLC (123797875)