

IBUPROFEN- ibuprofen tablet
Retail Business Services, LLC

Ibuprofen 200mg Tablets USP

Pain Reliever/ Fever Reducer (NSAID)

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

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.

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 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

- store between 20-25°C (68-77°F). [See USP Controlled Room Temperature].
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP

code #	:		
size	:	1+3/4 X 1+3/4 X 1+3/8	
ref #	:	PPL60E04E	7/16
material	:	.016 SBS	4/16

COATING
FREE AREA

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Drug Facts (continued)

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 disease, 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: • red, black, or tarry stools • vomit that is bloody or black
- you 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
- liver gets worse or lasts more than 5 days
- dizziness or swelling is present in the painful area

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Drug Facts (continued)

■ any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use, it is especially important not to use ibuprofen at 33 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. (1-800-325-1222)

Directions

■ do not take more than directed

■ the **route of 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

- store between 20-25°C (68-77°F). (See USP Controlled Room Temperature).
- avoid excessive heat above 40°C (104°F)

Inactive ingredients: colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone I-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

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Drug Facts (continued)

Questions or comments?
call 1-877-776-3843 Mon-Fri 8:00 AM EST to 9:00 PM PST

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Important: Read all the product information before use. Keep this leaflet for important information.

DO NOT USE IF FOIL INNER SEAL UNDER THE CAP IS BROKEN OR MISSING.

Drug Facts

Active ingredient (in each caplet): Ibuprofen 200 mg. **Purpose(s):** Pain reliever/fever reducer (NSAID)¹

Uses

- temporarily relieve minor aches and pains due to:
 - headache
 - muscle aches
 - minor pain of arthritis
 - toothache
 - backache
 - the common cold
 - menstrual cramps
- temporarily reduce 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 redness ■ rash ■ blisters

■ 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 thinner (anticoagulant) or stomach drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ use 3 or more alcoholic drinks every day while using this product

■ take more or for a longer time than directed

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Drug Facts (continued)

Questions or comments?
call 1-877-776-3843 Mon-Fri 8:00 AM EST to 9:00 PM PST

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Drug Facts (continued)

Questions or comments?
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Drug Facts (continued)

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Drug Facts (continued)

Questions or comments?
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Drug Facts (continued)

Questions or comments?
call 1-877-776-3843 Mon-Fri 8:00 AM EST to 9:00 PM PST

COATING
FREE AREA



code #	:
size	: 1+3/4 X 1+3/4 X 3+3/8
cat #	: PPL80604E
material	: 016 SBS

Drug Facts (continued)

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: • **red stool** • **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** • **nerve gets worse or lasts more than 3 days** • **numbness or tingling** is present in the painful area

Drug Facts (continued)

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. (1-800-222-1222)

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
- ask a doctor

Children under 12 years

- ask a doctor

Other information

- store between 20-25°C (68-77°F). (See USP Controlled Room Temperature).
- avoid excessive heat above 40°C (104°F).

Inactive ingredients: colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, polydioxane-10, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

CAREONE

IBUPROFEN

200 mg

Tablets USP

Pain Reliever/Fever Reducer (NSAID)*

50 COATED TABLETS

Actual Size

Compare to the Active Ingredient in Advil™

IND 72476-366-05

Important: Read all the product information before using. Keep this box for important information.

DO NOT USE IF FOIL LINER SEAL UNDER THE CAP IS BROKEN OR MISSING.

Drug Facts

Active ingredient (in each caplet): Ibuprofen 200 mg. Pain reliever/fever reducer (NSAID)*. Nonsteroidal anti-inflammatory drug.

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

Allegry alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: • **hives** • **facial swelling** • **asthma (wheezing)** • **shock** • **skin redness** • **rash** • **hives**

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**

Drug Facts (continued)

Questions or comments?

1-877-776-8183 (Mon-Fri 9:00 AM EST to 9:00 PM PST)

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-366
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
FERRIC OXIDE RED (UNII: 1K09F3G675)	

STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	brown ((Reddish Brown tablets))	Score	no score
Shape	OVAL ((Caplet shaped Tablets))	Size	14mm
Flavor		Imprint Code	G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-366-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
2	NDC:72476-366-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	07/26/2020	

Labeler - Retail Business Services, LLC (967989935)

Revised: 12/2023

Retail Business Services, LLC