IBUPROFEN- ibuprofen tablet CVS Pharmacy. Inc.

611R CVS 69842-493 Ibuprofen Tablets 200 mg

DRUG FACTS

Active ingredient (in each tablet)

Ibuprofen 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. 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 uses

adults and children 12 years and older	 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

• store at 20-25°C (68-77°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments? call **1-877-290-4008**

Exp Date: :.ON 10.1



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Drug Facts

Active ingredient (in each tablet) Purpose

200 mg (NSAID)*. Pain reliever/Fever reducer nonsteroidal anti-inflammatory drug

- **Uses** temporarily relieves minor aches and pains due to: headache → muscular aches → minor pain of arthritis • toothache • backache • the commor 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:

whives ■ facial swelling ■ asthma (wheezing)
■ shock ■ skin reddening ■ rash ■ blisters
If an allergic reaction occurs, stop use and seek

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

■ have had stomach ulcers or bleeding problems

■ take a blood thinning (anticoagulant) or steroid drug

■ take a blood transport production or secroid 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)

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
- 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 bloody of black stools
 have stomach pain that does not get better
 you have symptoms of heart problems or stroke: · chest pain · trouble breathing

uestions or comments? call 1-877-290-4008

talc, titanium dioxide polyvinyl alcohol,

Drug Facts (continued)

In 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

Directions

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

■ take 1 tablet every 4 to 6 hours adults and

while symptoms persist
if pain or fever does not respond
to 1 tablet, 2 tablets may be used children 12 years and older do not exceed 6 tablets in 24 hours, unless directed by a doctor

■ ask a doctor children under 12 years

Other information

■ store at 20-25°C (68-77°F)

Compare to the active ingredient in Motrin® IB Tablets** **Coated Tablets** 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

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).

CVSHealth

NDC 69842-493-01

Pain reliever/Fever reducer (NSAID) **FABLETS USP, 200 mg**

00 TABLETS

ackage Contains One Bottle

2514

CVS Health.

Coated Tablets

NDC 69842-493-01

TABLETS USP, 200 mg

Fever reducer (NSAID)

100 TABLETS

Pain reliever/

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

Usas ■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

Drug Facts (continued

active ingredients colloidal silicon dioxide, oscarmellose sodium, FD&C yellow #6 aluminum magnesium stearate, microcrystalline polyethylene glycol

Warnings Allengy alert: buprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include. ■ hives a facial swelling ■ asthmat witheacing) ■ shock ■ skin reddening ■ rash ■ bilsters. 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 may enther drug containing proscription no norprescription NSAIDs (aspirin, buprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be tatal. The risk is higher if you use more than directed or for longer than directed. If pregnant or breast-leading, 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 poverdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

Output

Directions

Output

Other

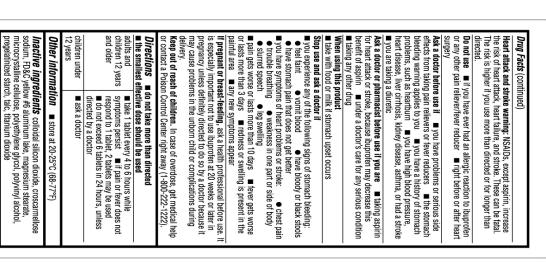
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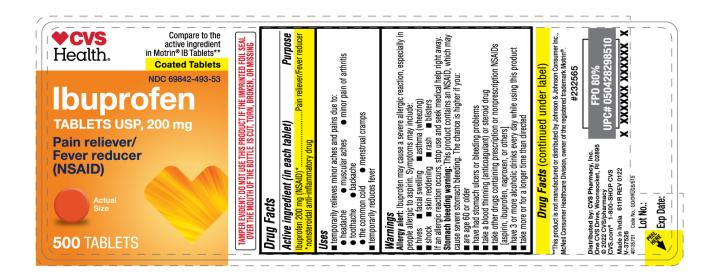
Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 **Questions or comments?** call **1-877-290-4008** 40136101 dode No.: GO/DRUGS/515 Made in India V-37526

611R REV 0122

Lot No.:

Exp Date:





IBUPROFEN

luestions or comments? call 1-877-290-4008

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-493
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg	

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
STARCH, CORN (UNII: O8232NY3SJ)				
TALC (UNII: 7SEV7J4R1U)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	115
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-493- 01	1 in 1 CARTON	05/23/2022	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-493- 53	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091237	05/23/2022	

Labeler - CVS Pharmacy. Inc. (062312574)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	manufacture(69842-493)	

Revised: 5/2022 CVS Pharmacy. Inc.