# IBUPROFEN- ibuprofen tablet, film coated H E B

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## **HEB Ibuprofen Tablets 200 mg Drug Facts**

## **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 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

**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 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).

#### **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

- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

### **Inactive ingredients**

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, iron oxides, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

#### **Questions or comments?**

1-800-719-9260

## **Principal Display Panel**

Compare to Motrin<sup>®</sup> IB Ibuprofen Caplets active ingredient

See New Warnings

Ibuprofen Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)

For Body Aches and Pains

actual size

50 COATED CAPLETS\*\*

\*\*Capsule-Shaped Tablets





1000 Promise

MADE WITH PRIDE & CARE FOR H-E-B \*\*
SAN ANTONIO, TX 78204

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- menstrual cramps
   temporarily reduces fever

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## Drug Facts (continued)

Ask a doctor before use if ■ you have problems or serious side effects from taking pain relie vers 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

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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
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- speech leg swelling pain gets worse or lasts more than 10 days
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  present in the painful area any new symptoms appear

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use ■ store at 20-25°C (68-77°F) ■ avoid high humidity and excessive heatabove 40°C (104°F)

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Questions or comments? 1-800-719-9260

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

KEEP CARTON FOR REFERENCE

## **IBUPROFEN**

ibuprofen tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37808-709

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

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

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
STARCH, CORN (UNII: O8232NY3SJ)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics				
Color	ORANGE	Score	no score	
Shape	OVAL	Size	14mm	
Flavor		Imprint Code	I2	
Contains				

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:37808-709-71	1 in 1 CARTON	08/21/2006	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077349	07/04/2006		

## **Labeler** - HEB (007924756)

Revised: 12/2019 HE B