

**IBUPROFEN- ibuprofen tablets usp, 200mg tablet  
KROGER COMPANY**

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**Kroger Ibuprofen Tablets USP, 200mg (Orange Caplets)**

***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:
  1. headache
  2. muscular aches
  3. minor pain of arthritis
  4. toothache
  5. backache
  6. the common cold
  7. 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:
  1. feel faint
  2. vomit blood
  3. have bloody or black stools
  4. have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  1. chest pain
  2. trouble breathing
  3. weakness in one part or side of body
  4. slurred speech
  5. 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**

- read all warnings and directions before use
- 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 **1-800-632-6900**

**Drug Facts**

**Purposes**

- Ibuprofen USP 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 common cold
  - menstrual cramps
- temporarily reduces fever

**Warnings**

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- 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**

- TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**
- read all warnings and directions before use
- store at 20-25°C (68-77°F)

**Questions or comments?** Call 1-800-632-6900

**MADE IN INDIA**

**\*OUR PHARMACIST RECOMMENDED**

612R 0324

LOT: \_\_\_\_\_

EXP: \_\_\_\_\_

**Varnish Omit Area**



## IBUPROFEN

ibuprofen tablets usp, 200mg tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41226-612
<b>Route of Administration</b>	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

<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Capsule shaped tablet)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	120
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-612-01	1 in 1 CARTON	04/15/2024	
1		100 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	ANDA091237	04/15/2024	

**Labeler** - KROGER COMPANY (006999528)

**Registrant** - TIME CAP LABORATORIES, INC (037052099)

### Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-612)