

**IBUPROFEN- ibuprofen tablet
WALGREENS**

Walgreens ibuprofen 200mg CAPLETS 612R

active ingredient

Solubilized Ibuprofen equal to

200 mg ibuprofen (NSAID)*

(present as the free acid and potassium salt)

* nonsteroidal anti-inflammatory drug

ibuprofen 200 mg CAPLETS 612R INACTIVE INGREDIENTS

Colloidal silicon dioxide, croscarmellose sodium, FD&C Yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

DO NOT TAKE MORE THAN DIRECTED

THE SMALLEST EFFECTIVE DOSE SHOULD BE USED

Adults and children 12 years and over:

- take 1 caplet every 4 to 6 hours while symptom persist
- If pain 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**

Temporarily relieves minor aches and pain due to :

- headache
- toothache
- backache

- menstrual cramps

- the common cold
- muscular aches
- minor pain of arthritis

Temporarily reduces fever

PAIN RELIEVER/ FEVER REDUCER

Allergy alert: Ibuprofen may cause a severe allergy reaction, especially in people allergic to aspirin. Symptoms may include:

asthma (wheezing)
blisters
facial swelling
hives
rash
shock

skin reddening

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

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

are age 60 or older

have bad stomach ulcers or bleeding problems

take a blood thinning (anticoagulant) or steroid drug

take other drugs containing prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

have 3 or more alcoholic drinks every day while using this product

the more or for a longer time than directed

Heart attack and stroke warning: NSAID's except aspirin increases the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or longer than directed.

IN CASE OF OVERDOSE, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY

50 COUNT 612R

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. The risk is higher if you have had an allergic reaction to aspirin or if you use more than directed for long-term treatment.

Use as directed: If you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer, do not take this or other aspirin.

Ask your doctor before use if:

- you have problems or serious side effects from taking pain relievers or fever reducers
- you have had 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 your doctor or pharmacist before use if you are:

- taking aspirin for heart attack or stroke, because together they decrease the risk of heart attack and stroke
- taking any other medicine for any other condition
- taking any other drug

When using this product:

- Stop use and ask a doctor if:
 - you experience any of the following signs of stomach bleeding:
 - heartburn
 - vomit that is dark or bloody or black stools
 - you have symptoms of heart problem or stroke
 - chest pain
 - trouble breathing
 - weakness in one part of the body
 - slurred speech
 - big swelling
 - your eyes become more than itchy
 - your gums bleed or bleed more than 10 days
 - your gums bleed or bleed more than 10 days

Keep out of reach of children. In case of overdose, get medical help or contact 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
 - Do not take more than 4 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°C to 25°C (68°F to 77°F)

Active ingredients:

- ibuprofen (NSAID)
- hydroxyethylcellulose
- polyvinyl alcohol
- propylated starch
- tinctorial
- yellow iron oxide

Questions or comments? Call 1-877-238-4888

Active Area

VALUE SIZE

Watkins

Compare to Motrin® 18 Caplets active ingredient

NDC 0063-9612-90

Ibuprofen 200

IBUPROFEN TABLETS USP, 200 mg / PAIN RELIEVER / FEVER REDUCER (NSAID)

CAPLETS

500 CA PLETS** (250 MSHALE-SHAPED TABLETS) ACTUAL SIZE

SEE NEW WARNINGS INFORMATION

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Active Area

Drug Facts (continued under label)

Warnings:

- Allergy alert: In people with a severe allergic reaction, especially in people allergic to aspirin, symptoms may not always include:
 - hives
 - facial swelling
 - asthma
 - difficulty breathing
- It is especially important not to use ibuprofen during the last 3 months of pregnancy unless clearly directed to do so by a doctor because it may cause problems in the unborn child or interfere with birth. In case of overdose, get medical help or contact Poison Control Center right away (1-800-222-1222).

Uses:

- Temporarily reduces fever
- Temporarily relieves:
 - minor aches and pains due to:
 - headache
 - muscle aches
 - pain of arthritis
 - the common cold
 - toothache

Directions:

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Lot No.: 1191720479

Exp. Date: 6

Remove Omit Area

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IBUPROFEN TABLETS USP, 200 mg / PAIN RELIEVER / FEVER REDUCER (NSAID)

500 CA PLETS** (250 MSHALE-SHAPED TABLETS) ACTUAL SIZE

SEE NEW WARNINGS INFORMATION

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9612
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH 1500, PREGELATINIZED (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	120
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9612-05	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
2	NDC:0363-9612-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
3	NDC:0363-9612-26	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
4	NDC:0363-9612-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA091237	12/11/2018	
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Labeler - WALGREENS (008965063)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(0363-9612)

Revised: 9/2018

WALGREENS