Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID) used to treat mild to moderate pain, and helps to relieve symptoms of arthritis (osteoarthritis, rheumatoid arthritis, or juvenile arthritis), such as inflammation, swelling, stiffness, and joint pain. This medicine does not cure arthritis and will help you only as long as you continue to take it.

In addition, ibuprofen can be used to treat fever, menstrual cramps, and other conditions as determined by your doctor.

This medicine is available both over-the-counter (OTC) and with your doctor's prescription.

This product is available in the following dosage forms:

- Suspension
- Tablet
Capsule, Liquid Filled
• Tablet, Chewable
• Capsule

Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of ibuprofen in children below 6 months of age. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatrics-specific problems that would limit the usefulness of ibuprofen in the elderly. However, elderly patients are more likely to have age-related kidney problems, which may require adjustment of dosage in patients receiving ibuprofen.

Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.
• Ketorolac

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

• Abciximab
• Aceclofenac
• Acemetacin
• Acenocoumarol
• Amiloride
• Aminoptine
• Amitriptyline
• Amitriptylineoxide
• Amoxapine
• Amtolmetin Guacil
• Anagrelide
• Apixaban
• Ardeparin
• Argatroban
• Aspirin
• Balsalazide
• Bemiparin
• Bendroflumethiazide
• Benzbthiazide
• Beta Glucan
• Betamethasone
• Bismuth Subsalicylate
• Bivalirudin
• Bromfenac
• Budesonide
• Bufexamac
• Bumetanide
• Cangrelor
• Celecoxib
• Certoparin
• Chlorothiazide
- Chlorthalidone
- Choline Magnesium Trisalicylate
- Choline Salicylate
- Cilostazol
- Citalopram
- Clomipramine
- Clonixin
- Clopamide
- Clopidogrel
- Cortisone
- Cyclopenthiazide
- Cyclosporine
- Dabigatran Etexilate
- Dalteparin
- Danaparoid
- Deflazacort
- Desipramine
- Desirudin
- Desvenlafaxine
- Dexamethasone
- Dexibuprofen
- Dexketoprofen
- Diazoxide
- Dibenzepin
- Diclofenac
- Diflunisal
- Digoxin
- Dipyridamole
- Dipyrone
- Dothiepin
- Doxepin
- Droxicam
- Duloxetine
- Edoxaban
- Enoxaparin
- Eplerenone
- Epoprostenol
- Eptifibatide
- Escitalopram
- Ethacrynic Acid
- Etodolac
- Etofenamate
- Etoricoxib
- Felbinac
- Fenoprofen
- Fepradinol
- Feprazone
- Feverfew
- Floctafenine
- Flufenamic Acid
- Fluocortolone
- Fluoxetine
- Flurbiprofen
- Fluvoxamine
- Fondaparinux
- Furosemide
- Ginkgo
- Gossypol
- Heparin
- Hydrochlorothiazide
- Hydrocortisone
- Hydroflumethiazide
- Ibuprofen
- Iloprost
- Imipramine
- Indapamide
- Indomethacin
- Ketoprofen
- Lepirudin
- Levomilnacipran
- Lithium
- Lofepramine
- Lornoxicam
- Loxoprofen
- Lumiracoxib
- Magnesium Salicylate
- Meadowsweet
- Meclofenamate
- Mefenamic Acid
- Melitracen
- Meloxicam
- Mesalamine
- Methotrexate
- Methyclothiazide
- Methylprednisolone
- Metolazone
- Milnacipran
- Morniflumate
- Nabumetone
- Nadroparin
- Naproxen
- Nefazodone
- Nepafenac
- Niflumic Acid
- Nimesulide
- Nimesulide Beta Cyclodextrin
- Nortriptyline
- Olsalazine
- Opipramol
- Oxaprozin
- Oxyphenbutazone
- Paramethasone
- Parendoxib
- Parnaparin
- Paroxetine
- Pemetrexed
- Pentosan Polysulfate Sodium
- Pentoxifylline
- Phenindione
- Phenprocoumon
- Phenylbutazone
- Phenyl Salicylate
- Piketoprofen
- Piroxicam
- Polythiazide
- Pralatrexate
- Prasugrel
- Prednisolone
- Prednisone
- Proglumetacin
- Propyphenazon
- Proquazone
- Protein C
- Protriptyline
- Reboxetine
- Reviparin
- Rivaroxaban
- Rofecoxib
- Salicylamide
- Salicylic Acid
- Salsalate
- Sertraline
- Sibutramine
- Sodium Salicylate
- Spironolactone
- Sulfasalazine
- Sulindac
- Tacrolimus
- Tenoxicam
- Tianeptine
- Tiaprofenic Acid
- Ticagrelor
- Ticlopidine
- Tinzaparin
- Tirofiban
- Tolfenamic Acid
- Tolmetin
- Torsemide
- Treprostinil
- Triamterene
- Trichlormethiazide
- Trimipramine
- Trolamine Salicylate
- Valdecoxib
- Venlafaxine
- Vilazodone
- Vorapaxar
- Vortioxetine
- Warfarin
- Xipamide

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Acebutolol
- Alacepril
- Amikacin
- Atenolol
- Azilsartan
- Azilsartan Medoxomil
- Benazepril
- Betaxolol
- Bisoprolol
- Candesartan
- Captopril
• Carteolol
• Carvedilol
• Celiprolol
• Cilazapril
• Delapril
• Enalapril
• Enalaprilat
• Eprosartan
• Esmolol
• Fosinopril
• Imidapril
• Irbesartan
• Labetalol
• Levobunolol
• Lisinopril
• Losartan
• Metipranolol
• Metoprolol
• Moexipril
• Nadolol
• Nebivolol
• Olmesartan
• Oxprenolol
• Penbutolol
• Pentopril
• Perindopril
• Pindolol
• Practolol
• Propranolol
• Quinapril
• Ramipril
• Sotalol
• Spirapril
• Telmisartan
• Temocapril
Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Anemia or
- Asthma or
- Bleeding problems or
- Blood clots or
- Edema (fluid retention or body swelling) or
- Heart attack, history of or
- Heart disease (e.g., congestive heart failure) or
- High blood pressure or
- Kidney disease or
- Liver disease (e.g., hepatitis) or
- Stomach or intestinal ulcers or bleeding or
- Stroke, history of—Use with caution. This medicine may make these conditions worse.
- Aspirin sensitivity, history of—This medicine should NOT be used in patients with this condition.
- Diabetes—Use with caution. The suspension form of this medicine contains sugar.
- Heart surgery (e.g., coronary artery bypass graft [CABG] surgery)—This medicine should NOT be used to relieve pain right before or after the surgery.

Proper Use

For safe and effective use of this medicine, do not take more of it, do not take it more often, and do not take it for a longer time than ordered by your doctor. Taking too much of this medicine may increase the chance of unwanted effects, especially in elderly patients.
When used for severe or continuing arthritis, this medicine must be taken regularly as ordered by your doctor in order for it to help you. This medicine usually begins to work within one week, but in severe cases up to two weeks or even longer may pass before you begin to feel better. Also, several weeks may pass before you feel the full effects of this medicine.

To lessen stomach upset, you may take this medicine with food or milk.

**Dosing**

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage form (tablets and suspension):
  - For fever:
    - Children over 2 years of age—Use and dose must be determined by your doctor.
    - Children 6 months of age up to 2 years—Dose is based on body weight and body temperature, and must be determined by your doctor. For fever lower than 102.5 °F (39.2 °C), the dose usually is 5 milligrams (mg) per kilogram (kg) (about 2.2 mg per pound) of body weight. For higher fever, the dose usually is 10 mg per kg (about 4.5 mg per pound) of body weight. The medicine may be given every six to eight hours, as needed, up to 40 mg per kg per day.
    - Infants younger than 6 months of age—Use and dose must be determined by your doctor.
  - For menstrual cramps:
    - Adults—400 milligrams (mg) every four hours, as needed.
    - Children—Use and dose must be determined by your doctor.
  - For mild to moderate pain:
    - Adults and teenagers—400 milligrams (mg) every four to six hours, as needed.
    - Children over 6 months of age—Dose is based on body weight and must be determined by your doctor. The dose usually is 10 milligrams (mg) per kilogram (kg) of body weight every six to eight hours, as needed, up to 40 mg per kg per day.
    - Infants younger than 6 months of age—Use and dose must be determined by your doctor.
  - For osteoarthritis and rheumatoid arthritis:
    - Adults and teenagers—1200 milligrams (mg) up to 3200 mg per day divided into three or four equal doses.
    - Children—Dose is based on body weight and must be determined by your doctor. The dose usually is 30 milligrams (mg) to 40 mg per kilogram (kg) of body weight per day.
divided into three or four doses.

- Infants younger than 6 months of age—Use and dose must be determined by your doctor.

**Missed Dose**

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

**Storage**

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

**Precautions**

It is very important that your doctor check your progress at regular visits. This will allow your doctor to see if the medicine is working properly and to decide if you should continue to take it. Blood and urine tests may be needed to check for unwanted effects.

This medicine may raise your risk of having a heart attack or stroke. This is more likely in people who already have heart disease. People who use this medicine for a long time might also have a higher risk.

This medicine may cause bleeding in your stomach or intestines. These problems can happen without warning signs. This is more likely if you have had a stomach ulcer in the past, if you smoke or drink alcohol regularly, if you are over 60 years old, if you are in poor health, or if you are using certain other medicines (a steroid or a blood thinner).

Serious skin reactions can occur during treatment with this medicine. Check with your doctor right away if you have any of the following symptoms while taking this medicine: blistering, peeling, loosening of skin, chills, cough, diarrhea, fever, itching, joint or muscle pain, red skin lesions, sore throat, sores, ulcers, white spots in mouth or on lips, or unusual tiredness or weakness.

Possible warning signs of some serious side effects that can occur during treatment with this medicine may include swelling of the face, fingers, feet, and/or lower legs; severe stomach pain, black, tarry stools, and/or vomiting of blood or material that looks like coffee grounds; unusual weight gain; yellow skin or eyes; decreased urination; bleeding or bruising; and/or skin rash. Also, signs of serious heart problems could occur such as chest pain, tightness in chest, fast or irregular heartbeat, unusual flushing or warmth of skin, weakness, or slurring of speech. Stop taking this medicine and check with your doctor immediately if you notice any of these warning signs.
This medicine may also cause a serious type of allergic reaction called anaphylaxis. Although this is rare, it may occur often in patients who are allergic to aspirin or other nonsteroidal anti-inflammatory drugs. Anaphylaxis requires immediate medical attention. The most serious signs of this reaction are very fast or irregular breathing, gasping for breath, wheezing, or fainting. Other signs may include changes in skin color of the face; very fast but irregular heartbeat or pulse; hive-like swellings on the skin; and puffiness or swelling of the eyelids or around the eyes. If these effects occur, get emergency help at once.

Some people who have used this medicine had symptoms of meningitis. If you have fever, headache, nausea, vomiting, and stiff neck or back while using this medicine, check with your doctor right away.

Using this medicine while you are pregnant can harm your unborn baby. If you think you have become pregnant while using this medicine, tell your doctor right away.

Check with your doctor immediately if blurred vision, difficulty in reading, or any other change in vision occurs during or after your treatment. Your doctor may want you to have your eyes checked by an ophthalmologist (eye doctor).

Before having any kind of surgery or medical tests, tell your doctor that you are taking this medicine. It may be necessary for you to stop treatment for a while, or to change to a different nonsteroidal anti-inflammatory drug before your procedure.

**Side Effects**

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

**More common**

- Abdominal pain
- acid or sour stomach
- belching
- bloating
- cloudy urine
- decrease in amount of urine
- decrease in urine output or decrease in urine-concentrating ability
- diarrhea
- difficulty having a bowel movement (stool)
- excess air or gas in stomach or intestines
- full feeling
- heartburn
• indigestion
• itching skin
• pain or discomfort in chest, upper stomach, or throat
• pale skin
• passing gas
• nausea
• noisy, rattling breathing
• rash with flat lesions or small raised lesions on the skin
• shortness of breath
• swelling of face, fingers, hands, feet, lower legs, or ankles
• troubled breathing at rest
• troubled breathing with exertion
• unusual bleeding or bruising
• unusual tiredness or weakness
• vomiting
• weight gain

Less common

• Abdominal cramps
• stomach soreness or discomfort

Rare

• Agitation
• back, leg, or stomach pains
• bleeding gums
• blistering, peeling, loosening of skin
• blood in urine or stools
• bloody, black, or tarry stools
• blurred vision
• burning feeling in chest or stomach
• change in vision
• chest pain
• chills
• clay-colored stools
• coma
• confusion
- constipation
- cough or hoarseness
- dark urine
- decreased urine output
- depression
- difficulty breathing
- difficulty swallowing
- dilated neck veins
- dizziness
- dry mouth
- extreme fatigue
- fast, irregular, pounding, or racing heartbeat or pulse
- fever with or without chills
- frequent urination
- general body swelling
- general feeling of tiredness or weakness
- hair loss, thinning of hair
- headache
- hives or welts
- hostility
- impaired vision
- increased blood pressure
- increased volume of pale, dilute urine
- irregular breathing
- irritability
- itching
- joint or muscle pain
- lab results that show problems with liver
- lethargy
- light-colored stools
- loss of appetite
- lower back or side pain
- muscle twitching
- nosebleeds
- painful or difficult urination
- pains in stomach, side, or abdomen, possibly radiating to the back
- pinpoint red spots on skin
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- rash
- red skin lesions, often with a purple center
- red, irritated eyes
- redness of skin
- seizures
- severe abdominal pain, cramping, burning
- severe and continuing nausea
- sore throat
- sores, ulcers, or white spots in mouth or on lips
- stiff neck or back
- stomach upset
- stupor
- swollen or painful glands
- tenderness in stomach area
- thirst
- tightness in chest
- unpleasant breath odor
- upper right abdominal pain
- vomiting of blood
- vomiting of material that looks like coffee grounds
- wheezing
- yellow eyes and skin

**Symptoms of overdose**

- Bluish lips or skin
- difficulty sleeping
- disorientation
- dizziness, faintness, or lightheadedness when getting up from a lying or sitting position suddenly
- drowsiness to profound coma
- hallucination
- lightheadedness or fainting
- mood or other mental changes
• muscle tremors
• not breathing
• rapid, deep breathing
• restlessness
• slow or irregular heartbeat
• stomach cramps
• sudden fainting
• sweating

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

• Continuing ringing or buzzing or other unexplained noise in ears
• hearing loss
• nervousness

Rare

• Crying
• depersonalization
• discouragement
• dry eyes
• dysphoria
• euphoria
• feeling sad or empty
• lack of appetite
• loss of interest or pleasure
• mental depression
• paranoia
• quick to react or overreact
• rapidly changing moods
• runny nose
• sleepiness or unusual drowsiness
• sleeplessness
• sneezing
- stuffy nose
- trouble concentrating
- trouble sleeping
- unable to sleep

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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