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Ibuprofen

pronounced as (eye byoo' proe fen)

IMPORTANT WARNING:

People who take nonsteroidal anti-inflammatory drugs (NSAIDs) (other than aspirin) such as ibuprofen may have a higher risk of having a heart attack or a stroke than people who do not take these medications. These events may happen without warning and may cause death. This risk may be higher for people who take NSAIDs for a long time. Tell your doctor if you or anyone in your family has or has ever had heart disease, a heart attack, or a stroke; if you smoke; and if you have or have ever had high cholesterol, high blood pressure, or diabetes. Get emergency medical help right away if you experience any of the following symptoms: chest pain, shortness of breath, weakness in one part or side of the body, or slurred speech.

If you will be undergoing a coronary artery bypass graft (CABG; a type of heart surgery), you should not take ibuprofen right before or right after the surgery.

NSAIDs such as ibuprofen may cause ulcers, bleeding, or holes in the stomach or intestine. These problems may develop at any time during treatment, may happen without warning symptoms, and may cause death. The risk may be higher for people who take NSAIDs for a long time, are older in age, have poor health, or who drink three or more alcoholic drinks per day while taking ibuprofen. Tell your doctor if you take any of the following medications: anticoagulants ('blood thinners') such as warfarin (Coumadin); aspirin; other NSAIDs such as ketoprofen (Orudis KT, Actron) and naproxen (Aleve, Naprosyn); or oral steroids such as dexamethasone (Decadron, Dexone), methylprednisolone (Medrol), and prednisone (Deltasone). Also tell your doctor if you have or have ever had ulcers, bleeding in your stomach or intestines, or other bleeding disorders. If you experience any of the following symptoms, stop taking ibuprofen and call your doctor: stomach pain, heartburn, vomit that is bloody or looks like coffee grounds, blood in the stool, or black and tarry stools.

Keep all appointments with your doctor and the laboratory. Your doctor will monitor your symptoms carefully and will probably order certain tests to check your body's response to ibuprofen. Be sure to tell your doctor how you are feeling so that your doctor can prescribe the right amount of medication to treat your condition with the lowest risk of serious side effects.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with prescription ibuprofen and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Why is this medication prescribed?

Prescription ibuprofen is used to relieve pain, tenderness, swelling, and stiffness caused by osteoarthritis (arthritis caused by a breakdown of the lining of the joints) and rheumatoid arthritis (arthritis caused by swelling of the lining of the joints). It is also used to relieve mild to moderate pain, including menstrual pain (pain that happens before or during a menstrual period). Nonprescription ibuprofen is used to reduce fever and to relieve minor aches and pain from headaches, muscle aches, arthritis, menstrual periods,

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the common cold, toothaches, and backaches. Ibuprofen is in a class of medications called NSAIDs. It works by stopping the body's production of a substance that causes pain, fever, and inflammation.

How should this medicine be used?

Prescription ibuprofen comes as a tablet to take by mouth. It is usually taken three or four times a day for arthritis or every 4 to 6 hours as needed for pain. Nonprescription ibuprofen comes as a tablet, chewable tablet, suspension (liquid), and drops (concentrated liquid). Adults and children older than 12 years of age may usually take nonprescription ibuprofen every 4 to 6 hours as needed for pain or fever. Children and infants may usually be given nonprescription ibuprofen every 6 to 8 hours as needed for pain or fever, but should not be given more than 4 doses in 24 hours. Ibuprofen may be taken with food or milk to prevent stomach upset. If you are taking ibuprofen on a regular basis, you should take it at the same time(s) every day. Follow the directions on the package or prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ibuprofen exactly as directed. Do not take more or less of it or take it more often than directed by the package label or prescribed by your doctor.

Ibuprofen comes alone and in combination with other medications. Some of these combination products are available by prescription only, and some of these combination products are available without a prescription and are used to treat cough and cold symptoms and other conditions. If your doctor has prescribed a medication that contains ibuprofen, you should be careful not to take any nonprescription medications that also contain ibuprofen.

If you are selecting a product to treat cough or cold symptoms, ask your doctor or pharmacist for advice on which product is best for you. Check nonprescription product labels carefully before using two or more products at the same time. These products may contain the same active ingredient(s) and taking them together could cause you to receive an overdose. This is especially important if you will be giving cough and cold medications to a child.

Nonprescription cough and cold combination products, including products that contain ibuprofen, can cause serious side effects or death in young children. Do not give these products to children younger than 4 years of age. If you give these products to children 4 to 11 years of age, use caution and follow the package directions carefully.

If you are giving ibuprofen or a combination product that contains ibuprofen to a child, read the package label carefully to be sure that it is the right product for a child of that age. Do not give ibuprofen products that are made for adults to children.

Before you give an ibuprofen product to a child, check the package label to find out how much medication the child should receive. Give the dose that matches the child's age on the chart. Ask the child's doctor if you don't know how much medication to give the child.

Shake the suspension and drops well before each use to mix the medication evenly. Use the measuring cup provided to measure each dose of the suspension, and use the dosing device provided to measure each dose of the drops.

The chewable tablets may cause a burning feeling in the mouth or throat. Take the chewable tablets with food or water.

Stop taking nonprescription ibuprofen and call your doctor if your symptoms get worse, you develop new or unexpected symptoms, the part of your body that was painful becomes red or swollen, your pain lasts for more than 10 days, or your fever lasts more than 3 days. Stop giving nonprescription ibuprofen to your child and call your child's doctor if your child does not start to feel better during the first 24 hours of treatment. Also stop giving nonprescription ibuprofen to your child and call your child's doctor if your child develops new symptoms, including redness or swelling on the painful part of his body, or if your child's pain or fever get worse or lasts longer than 3 days.

Do not give nonprescription ibuprofen to a child who has a sore throat that is severe or does not go away, or that comes along with fever, headache, nausea, or vomiting. Call the child's doctor right away, because these symptoms may be signs of a more serious condition.

Other uses for this medicine

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Ibuprofen is also sometimes used to treat ankylosing spondylitis (arthritis that mainly affects the spine), gouty arthritis (joint pain caused by a build-up of certain substances in the joints), and psoriatic arthritis (arthritis that occurs with a long-lasting skin disease that causes scaling and swelling). Talk to your doctor about the risks of using this drug for your condition.

This medication is sometimes prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking ibuprofen,

- tell your doctor and pharmacist if you are allergic to ibuprofen, aspirin or other NSAIDs such as ketoprofen (Orudis KT, Actron) and naproxen (Aleve, Naprosyn), any other medications, or any of the inactive ingredients in the type of ibuprofen you plan to take. Ask your pharmacist or check the label on the package for a list of the inactive ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: angiotensin-converting enzyme (ACE) inhibitors such as benazepril (Lotensin), captopril (Capoten), enalapril (Vasotec), fosinopril (Monopril), lisinopril (Prinivil, Zestril), moexipril (Univasc), perindopril (Aceon), quinapril (Accupril), ramipril (Altace), and trandolapril (Mavik); diuretics ('water pills'); lithium (Eskalith, Lithobid); and methotrexate (Rheumatrex). Your doctor may need to change the doses of your medications or monitor you more carefully for side effects.
- do not take nonprescription ibuprofen with any other medication for pain unless your doctor tells you that you should.
- tell your doctor if you have or have ever had any of the conditions mentioned in the IMPORTANT WARNING section or asthma, especially if you also have frequent stuffed or runny nose or nasal polyps (swelling of the inside of the nose); swelling of the hands, arms, feet, ankles, or lower legs; lupus (a condition in which the body attacks many of its own tissues and organs, often including the skin, joints, blood, and kidneys); or liver or kidney disease. If you are giving ibuprofen to a child, tell the child's doctor if the child has not been drinking fluids or has lost a large amount of fluid from repeated vomiting or diarrhea.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy; you plan to become pregnant; or you are breast-feeding. If you become pregnant while taking ibuprofen, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking ibuprofen.
- if you have phenylketonuria (PKU, an inborn disease in which mental retardation develops if a specific diet is not followed), read the package label carefully before taking nonprescription ibuprofen. Some types of nonprescription ibuprofen may be sweetened with aspartame, a source of phenylalanine.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you are taking ibuprofen on a regular basis, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Ibuprofen may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- constipation
- diarrhea
- gas or bloating
- dizziness
- nervousness
- ringing in the ears

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Some side effects can be serious. If you experience any of the following symptoms, or those mentioned in the IMPORTANT WARNING section, call your doctor immediately. Do not take any more ibuprofen until you speak to your doctor.

- unexplained weight gain
- fever
- blisters
- rash
- itching
- hives
- swelling of the eyes, face, throat, arms, hands, feet, ankles, or lower legs
- difficulty breathing or swallowing
- hoarseness
- excessive tiredness
- pain in the upper right part of the stomach
- nausea
- loss of appetite
- yellowing of the skin or eyes
- flu-like symptoms
- pale skin
- fast heartbeat
- cloudy, discolored, or bloody urine
- back pain
- difficult or painful urination
- blurred vision, changes in color vision, or other vision problems
- red or painful eyes
- stiff neck
- headache
- confusion
- aggression

Ibuprofen may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]] or by phone [1-800-332-1088].

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

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In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- dizziness
- fast eye movements that you cannot control
- slow breathing or short periods of time without breathing
- blue color around the lips, mouth, and nose

What other information should I know?

If you are taking prescription ibuprofen, do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Addaprin ®
- Advil ®
- Caldolor ®
- Cedaprin ®

- I-Prin ®
- Midol ®
- Motrin ®
- Motrin ® IB

- NeoProfen ®
- Profen IB ®
- Proprinal ®
- Ultraprin ®

Brand names of combination products

- Advil ® PM (containing Diphenhydramine, Ibuprofen)
- Combunox ® (containing Ibuprofen, Oxycodone) ¶
- Duexis ® (containing Famotidine, Ibuprofen)

- Ibudone ® (containing Hydrocodone, Ibuprofen)
- Reprexain ® (containing Hydrocodone, Ibuprofen)

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- Vicoprofen ® (containing Hydrocodone, Ibuprofen)

¶ - This branded product is no longer on the market. Generic alternatives may be available.

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