IBU tablets contain the active ingredient ibuprofen, which is (±)-2-(p-isobutylphenyl) propionic acid. Ibuprofen is a white powder with a melting point of 74-77°C and is very slightly soluble in water (<1 mg/mL) and readily soluble in organic solvents such as ethanol and acetone. The structural formula is represented below:

\[
\text{Structure}
\]

IBU, a nonsteroidal anti-inflammatory drug (NSAID), is available in 400 mg, 600 mg, and 800 mg tablets for oral administration. Inactive ingredients: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, polysorbate, titanium dioxide.

IBU tablets contain ibuprofen which possesses analgesic and antipyretic activities. Its mode of action, like that of other NSAIDs, is not completely understood, but may be related to prostaglandin synthetase inhibition.

In clinical studies in patients with rheumatoid arthritis and osteoarthritis, ibuprofen tablets have been shown to be comparable to aspirin in controlling pain and inflammation and to be associated with a statistically significant reduction in the milder gastrointestinal side effects (see ADVERSE REACTIONS). Ibuprofen may be well tolerated in some patients who have had gastrointestinal side effects with aspirin, but these patients when treated with IBU tablets should be carefully followed for signs and symptoms of gastrointestinal ulceration and bleeding. Although it is not definitely known whether ibuprofen causes less peptic ulceration than aspirin, in one study involving 885 patients with rheumatoid arthritis treated for up to one year, there were no reports of gastric ulceration with ibuprofen whereas frank ulceration was reported in 13 patients in the aspirin group (statistically significant p < .001).

Gastroscopic studies at varying doses show an increased tendency toward gastric irritation at higher doses. However, at comparable doses, gastric irritation is approximately half that seen with aspirin. Studies using 51Cr-tagged red cells indicate that fecal blood loss associated with ibuprofen tablets in doses up to 2400 mg daily did not exceed the normal range, and was significantly less than that seen in aspirin-treated patients.

In clinical studies in patients with rheumatoid arthritis, ibuprofen has been shown to be comparable to
indomethacin in controlling the signs and symptoms of disease activity and to be associated with a statistically significant reduction of the milder gastrointestinal (see ADVERSE REACTIONS) and CNS side effects.

Ibuprofen may be used in combination with gold salts and/or corticosteroids.

Controlled studies have demonstrated that Ibuprofen is a more effective analgesic than propoxyphene for the relief of episiotomy pain, pain following dental extraction procedures, and for the relief of the symptoms of primary dysmenorrhea.

In patients with primary dysmenorrhea, Ibuprofen has been shown to reduce elevated levels of prostaglandin activity in the menstrual fluid and to reduce resting and active intrauterine pressure, as well as the frequency of uterine contractions. The probable mechanism of action is to inhibit prostaglandin synthesis rather than simply to provide analgesia.

The ibuprofen in IBU tablets is rapidly absorbed. Peak serum ibuprofen levels are generally attained one to two hours after administration. With single doses up to 800 mg, a linear relationship exists between amount of drug administered and the integrated area under the serum drug concentration vs time curve. Above 800 mg, however, the area under the curve increases less than proportionally to increases in dose. There is no evidence of drug accumulation or enzyme induction.

The administration of Ibuprofen tablets either under fasting conditions or immediately before meals yields quite similar serum ibuprofen concentration-time profiles. When Ibuprofen is administered immediately after a meal, there is a reduction in the rate of absorption but no appreciable decrease in the extent of absorption. The bioavailability of the drug is minimally altered by the presence of food.

A bioavailability study has shown that there was no interference with the absorption of ibuprofen when given in conjunction with an antacid containing both aluminum hydroxide and magnesium hydroxide.

Ibuprofen is rapidly metabolized and eliminated in the urine. The excretion of ibuprofen is virtually complete 24 hours after the last dose. The serum half-life is 1.8 to 2.0 hours.

Studies have shown that following ingestion of the drug, 45% to 79% of the dose was recovered in the urine within 24 hours as metabolite A (25%), (+)-2-[p-(2-hydroxymethyl-propyl) phenyl] propionic acid and metabolite B (37%), (+)-2-[p-(2-carboxypropyl) phenyl] propionic acid; the percentages of free and conjugated ibuprofen were approximately 1% and 14%, respectively.

Carefully consider the potential benefits and risks of Ibuprofen tablets and other treatment options before deciding to use Ibuprofen. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see WARNINGS).

IBU tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.

IBU tablets are indicated for relief of mild to moderate pain.

IBU tablets are also indicated for the treatment of primary dysmenorrhea.

Controlled clinical trials to establish the safety and effectiveness of IBU tablets in children have not been conducted.

IBU tablets are contraindicated in patients with known hypersensitivity to ibuprofen.

IBU tablets should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients (see WARNINGS, ANAPHYLACTOID REACTIONS, and PRECAUTIONS, PREEXISTING ASTHMA).

IBU tablets are contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see WARNINGS).

General

IBU tablets cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency.
Abrupt discontinuation of corticosteroids may lead to disease exacerbation. Patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids.

The pharmacological activity of IBU tablets in reducing fever and inflammation may diminish the utility of these diagnostic signs in detecting complications of presumed noninfectious, painful conditions.

**Hepatic effects**
Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs, including IBU tablets. These laboratory abnormalities may progress, may remain unchanged, or maybe transient with continuing therapy. Notable elevations of ALT or AST (approximately three or more times the upper limit of normal) have been reported in approximately 1% of patients in clinical trials with NSAIDs. In addition, rare cases of severe hepatic reactions, including jaundice, fulminant hepatitis, liver necrosis, and hepatic failure, some of them with fatal outcomes have been reported. A patient with symptoms and/or signs suggesting liver dysfunction, or with abnormal liver test values, should be evaluated for evidence of the development of a more severe hepatic reaction while on therapy with IBU tablets. If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash, etc.), IBU tablets should be discontinued.

**Hematological effects**
Anemia is sometimes seen in patients receiving NSAIDs, including IBU tablets. This may be due to fluid retention, occult or gross GI blood loss, or an incompletely described effect upon erythropoiesis. Patients on long-term treatment with NSAIDs, including IBU tablets, should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia.

In two postmarketing clinical studies the incidence of a decreased hemoglobin level was greater than previously reported. Decrease in hemoglobin of 1 gram or more was observed in 17.1% of 193 patients on 1600 mg ibuprofen daily (osteoarthritis), and in 22.8% of 189 patients taking 2400 mg of ibuprofen daily (rheumatoid arthritis). Positive stool occult blood tests and elevated serum creatinine levels were also observed in these studies.

NSAIDs inhibit platelet aggregation and have been shown to prolong bleeding time in some patients. Unlike aspirin, their effect on platelet function is quantitatively less, of shorter duration, and reversible.

Patients receiving IBU tablets who may be adversely affected by alterations in platelet function, such as those with coagulation disorders or patients receiving anticoagulants should be carefully monitored.

**Preexisting asthma**
Patients with asthma may have aspirin-sensitive asthma. The use of aspirin in patients with aspirin-sensitive asthma has been associated with severe bronchospasm which can be fatal. Since cross reactivity, including bronchospasm, between aspirin and NSAIDs has been reported in such aspirin-sensitive patients, IBU tablets should not be administered to patients with this form of aspirin sensitivity and should be used with caution in patients with preexisting asthma.

**Ophthalmological effects.**
Blurred and/or diminished vision, scotomata, and/or changes in color vision have been reported. If a patient develops such complaints while receiving IBU tablets, the drug should be discontinued, and the patient should have an ophthalmologic examination which includes central visual fields and color vision testing.

**Aseptic Meningitis**
Aseptic meningitis with fever and coma has been observed on rare occasions in patients on ibuprofen therapy. Although it is probably more likely to occur in patients with systemic lupus erythematosus and related connective tissue diseases, it has been reported in patients who do not have an underlying chronic disease. If signs or symptoms of meningitis develop in a patient on IBU tablets, the possibility of its being related to IBU tablets should be considered.

**Information for Patients**
Patients should be informed of the following information before initiating therapy with an NSAID and periodically during the course of ongoing therapy. Patients should also be encouraged to read the NSAID Medication Guide that accompanies each prescription dispensed.

- IBU tablets like other NSAIDs, may cause serious CV side effects, such as MI or stroke, which may result in hospitalization and even death. Although serious CV events can occur without warning symptoms, patients should be alert for the signs and symptoms of chest pain, shortness of breath, weakness, slurring of speech, and should ask for medical advice when observing any indicative signs or symptoms. Patients should be apprised of the importance of this follow-up (see WARNINGS, CARDIOVASCULAR EFFECTS).

- IBU tablets, like other NSAIDs, can cause GI discomfort and, rarely, serious GI side effects, such as ulcers and bleeding, which may result in hospitalization and even death. Although serious GI tract ulcerations and bleeding can occur without warning symptoms, patients should be alert for the signs and symptoms of ulcerations and bleeding, and should ask for medical advice when observing any indicative signs or symptoms including epigastric pain, dyspepsia, melena, and hematemesis. Patients should be apprised of the importance of this follow-up (see WARNINGS, GASTROINTESTINAL EFFECTS - RISK OF ULCERATION, BLEEDING AND PERFORATION).

- IBU tablets, like other NSAIDs, can cause serious skin side effects such as exfoliative dermatitis, SJS and TEN, which may result in hospitalization and even death. Although serious skin reactions may occur without warning, patients should be alert for the signs and symptoms of skin rash and blisters, fever, or other signs of hypersensitivity such as itching, and should ask for medical advice when observing any indicative sign or symptoms. Patients should be advised to stop the drug immediately if they develop any type of rash and contact their physicians as soon as possible.

- Patients should promptly report signs or symptoms of unexplained weight gain or edema to their physicians.

- Patients should be informed of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, jaundice, right upper quadrant tenderness and “flu-like” symptoms). If these occur, patients should be instructed to stop therapy and seek immediate medical therapy.

- Patients should be informed of the signs of an anaphylactoid reaction (e.g., difficulty breathing, swelling of the face or throat). If these occur, patients should be instructed to seek immediate emergency help (see WARNINGS).

- In late pregnancy, as with other NSAIDs, IBU tablets should be avoided because it may cause premature closure of the ductus arteriosus.

Laboratory Tests
Because serious GI tract ulcerations and bleeding can occur without warning symptoms, physicians should monitor for signs or symptoms of GI bleeding. Patients on long-term treatment with NSAIDs should have their CBC and chemistry profile checked periodically. If clinical signs and symptoms consistent with liver or renal disease develop, systemic manifestations occur (e.g., eosinophilia, rash etc.), or abnormal liver tests persist or worsen, IBU tablets should be discontinued.

Drug Interactions
ACE-inhibitors: Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE-inhibitors. This interaction should be given consideration in patients taking NSAIDs concomitantly with ACE-inhibitors.

Aspirin: When IBU tablets are administered with aspirin, its protein binding is reduced, although the clearance of free IBU tablets is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of ibuprofen and aspirin is not generally recommended because of the potential for increased adverse effects.

Diuretics
Clinical studies, as well as post marketing observations, have shown that ibuprofen tablets can reduce
the natriuretic effect-offurosemide and thiazides in some patients. This response has beenattributed to inhibition of renal prostaglandin synthesis. During concomitanttherapy with NSAIDs, the patient should be observed closelyfor signs of renal failure (see PRECAUTIONS, Renal Effects), aswell as to assure diuretic efficacy.

Lithium
Ibuprofen produced an elevation of plasma lithium levels and areduction in renal lithium clearance in a study of eleven normal volunteers. The mean minimum lithium concentration increased 15%and the renal clearance of lithium was decreased by 19% during thisperiod of concomitant drug administration. This effect has been attributed to inhibition of renal prostaglandin synthesis by ibuprofen. Thus, when ibuprofen and lithium are administeredconcurrently, subjects should be observed carefully for signsof lithium toxicity. (Read circulars for lithium preparation before useof such concurrent therapy.)

Methotrexate
NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This may indicate that they couldenhance the toxicity of methotrexate. Caution should be used when NSAIDs are administered concomitantly with methotrexate.

Warfarin-type anticoagulants
Several short-term controlled studies failed to show that Ibuprofentablets significantly affected prothrombin times or a variety of other clotting factors when administered to individuals on coumarin-type anticoagulants. However, because bleeding has been reported when IBU tablets and other NSAIDs have been administered to patients on coumarin-type anticoagulants, the physician should be cautious when administering IBU tablets to patients on anticoagulants. The effects of warfarin and NSAIDs on GI bleeding are synergistic, such that the users of both drugs together have a risk of serious GI bleeding higher than users of either drug alone.

H-2 Antagonists
In studies with human volunteers, co-administration of cimetidine or ranitidine with ibuprofen had no substantive effect on ibuprofen serum concentrations.

Pregnancy
Teratogenic effects: Pregnancy Category C
Reproductive studies conducted in rats and rabbits have not demonstrated evidence of developmental abnormalities. However, animal reproduction studies are not always predictive of human response. There are no adequate and well-controlled studies in pregnant women. Ibuprofen should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic effects
Because of the known effects of NSAIDs on the fetal cardiovascular system (closure of ductus arteriosus), use during late pregnancy should be avoided.

Labor and Delivery
In rat studies with NSAIDs, as with other drugs known to inhibit prostaglandin synthesis, an increased incidence of dystocia, delayed parturition, and decreased pup survival occurred. The effects of IBU tablets on labor and delivery in pregnant women are unknown.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from IBU tablets, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use
Safety and effectiveness of IBU tablets in pediatric patients have not been established.
Geriatric Use

As with any NSAIDs, caution should be exercised in treating the elderly (65 years and older).

The most frequent type of adverse reaction occurring with ibuprofen tablets is gastrointestinal. In controlled clinical trials the percentage of patients reporting one or more gastrointestinal complaints ranged from 4% to 16%.

In controlled studies when ibuprofen tablets were compared to aspirin and indomethacin in equally effective doses, the overall incidence of gastrointestinal complaints was about half that seen in either the aspirin- or indomethacin-treated patients.

Adverse reactions observed during controlled clinical trials at an incidence greater than 1% are listed in the table. Those reactions listed in Column one encompass observations in approximately 3,000 patients. More than 500 of these patients were treated for periods of at least 54 weeks.

Still other reactions occurring less frequently than 1 in 100 were reported in controlled clinical trials and from marketing experience. These reactions have been divided into two categories: Column two of the table lists reactions with therapy with ibuprofen tablets where the probability of a causal relationship exists: for the reactions in Column three, a causal relationship with ibuprofen tablets has not been established.

Reported side effects were higher at doses of 3200 mg/day than at doses of 2400 mg or less per day in clinical trials of patients with rheumatoid arthritis. The increases in incidence were slight and still within the ranges reported in the table.

Approximately 1 1/2 hours after the reported ingestion of from 7 to 10 ibuprofen tablets (400 mg), a 19-month old child weighing 12 kg was seen in the hospital emergency room, apneic and cyanotic, responding only to painful stimuli. This type of stimulus, however, was sufficient to induce respiration. Oxygen and parenteral fluids were given; a greenish-yellow fluid was aspirated from the stomach with no evidence to indicate the presence of ibuprofen. Two hours after ingestion the child's condition seemed stable; she still responded only to painful stimuli and continued to have periods of apnea lasting from 5 to 10 seconds. She was admitted to intensive care and sodium bicarbonate was administered as well as infusions of dextrose and normal saline. By four hours post-ingestion she could bearoused easily, sit by herself and respond to spoken commands. Blood level of ibuprofen was 102.9 μg/mL approximately 8 1/2 hours after accidental ingestion. At 12 hours she appeared to be completely recovered.

In two other reported cases where children (each weighing approximately 10 kg) accidentally, acutely ingested approximately 120 mg/kg, there were no signs of acute intoxication or late sequelae. Blood level in one child 90 minutes after ingestion was 700 μg/mL —about 10 times the peak levels seen in absorption-excretion studies. A 19-year old male who had taken 8,000 mg of ibuprofen over a period of a few hours complained of dizziness, and nystagmus was noted. After hospitalization, parenteral hydration and three days bedrest, he recovered with no reported sequelae.

In cases of acute overdosage, the stomach should be emptied by vomiting or lavage, though little drug will likely be recovered if more than an hour has elapsed since ingestion. Because the drug is acidic and is excreted in the urine, it is theoretically beneficial to administer alkali and induce diuresis. In addition to supportive measures, the use of oral activated charcoal may help to reduce the absorption and reabsorption of ibuprofen tablets.

Carefully consider the potential benefits and risks of IBU tablets and other treatment options before deciding to use IBU tablets. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see WARNINGS).

After observing the response to initial therapy with IBU tablets, the dose and frequency should be adjusted to suit an individual patient’s needs. Do not exceed 3200 mg total daily dose. If gastrointestinal
complaints occur, administer IBU tablets with meals or milk.

Rheumatoid arthritis and osteoarthritis, including flare-ups of chronic disease:
Suggested Dosage: 1200 mg-3200 mg daily (400 mg, 600 mg or 800 mg tid or qid). Individual patients may show a better response to 3200 mg daily, as compared with 2400 mg, although in well-controlled clinical trials patients on 3200 mg did not show a better mean response in terms of efficacy. Therefore, when treating patients with 3200 mg/day, the physician should observe sufficient increased clinical benefits to offset potential increased risk. The dose should be tailored to each patient, and may be lowered or raised depending on the severity of symptoms either at time of initiating drug therapy or as the patient responds or fails to respond. In general, patients with rheumatoid arthritis seem to require higher doses of IBU tablets than do patients with osteoarthritis.

The smallest dose of IBU tablets that yields acceptable control should be employed. A linear blood level dose-response relationship exists with single doses up to 800 mg (See CLINICAL PHARMACOLOGY for effects of food on rate of absorption).

The availability of three tablet strengths facilitates dosage adjustment. In chronic conditions, a therapeutic response to therapy with IBU tablets is sometimes seen in a few days to a week but most often is observed by two weeks. After a satisfactory response has been achieved, the patient’s dose should be reviewed and adjusted as required.

Mild to moderate pain:
400 mg every 4 to 6 hours as necessary for relief of pain. In controlled analgesic clinical trials, doses of Ibuprofen tablets greater than 400 mg were no more effective than the 400 mg dose.

Dysmenorrhea:
For the treatment of dysmenorrhea, beginning with the earliest onset of such pain, IBU tablets should be given in a dose of 400 mg every 4 hours as necessary for the relief of pain.

Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
(See the end of this Medication Guide for a list of prescription NSAID medicines.)

What is the most important information I should know about medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

NSAID medicines may increase the chance of a heart attack or stroke that can lead to death. This chance increases:
• with longer use of NSAID medicines • in people who have heart disease

NSAID medicines should never be used right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

NSAID medicines can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Ulcers and bleeding:
• can happen without warning symptoms • may cause death

The chance of a person getting an ulcer or bleeding increases with:
• taking medicines called “corticosteroids” • drinking alcohol and “anticoagulants”
• older age
• longer use • having poor health
• smoking

NSAID medicines should only be used:
• exactly as prescribed
• for the shortest time needed
• at the lowest dose possible for your treatment

What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

NSAID medicines are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as:

• different types of arthritis
• menstrual cramps and other types of short-term pain

Who should not take a Non-Steroidal Anti-Inflammatory Drug (NSAID)? Do not take an NSAID medicine:

• if you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine
• for pain right before or after heart bypass surgery

Tell your healthcare provider:

• about all of your medical conditions
• about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects.

Keep a list of your medicines to show to your healthcare provider and pharmacist.

• if you are pregnant. NSAID medicines should not be used by pregnant women late in their pregnancy.
• if you are breastfeeding. Talk to your doctor.

What are the possible side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

Serious side effect Other side effect include

• heart attack • stomach pain
• stroke • constipation
• high blood pressure • diarrhea
• heart failure from body swelling (fluid retention) • gas
• kidney problems including kidney failure • heartburn
• bleeding and ulcers in the stomach and intestine • nausea
• low red blood cells (anemia) • vomiting
• life-threatening skin reactions • dizziness
• life-threatening allergic reactions
• liver problems including liver failure
• asthma attacks in people who have asthma

Get emergency help right away if you have any of the following symptoms:

• shortness of breath or trouble breathing • slurred speech
• chest pain • swelling of the face or throat
• weakness in one part or side of your body

Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms:

• nausea • vomit blood
• more tired or weaker than usual • there is blood in your bowel movement or sticky it is black and sticky like tar
• itching • skin rash or blister with fever
• your skin or eyes look yellow • unusual weight gain
• stomach pain • swelling of the arms and legs, hands and feet
• flu-like symptoms

These are not all the side effects with NSAID medicines. Talk to your healthcare provider or
pharmacist for more information about NSAID medicines.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. Other information about Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

- Aspirin is an NSAID medicine but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.

- Some of these NSAID medicines are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

**NSAID medicines that need a prescription**

<table>
<thead>
<tr>
<th>Generic</th>
<th>Trade Name</th>
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<tbody>
<tr>
<td>Celecoxib</td>
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<tr>
<td>Diclofenac</td>
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<td>Diflunisal</td>
<td>Dolobid</td>
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<tr>
<td>Etodolac</td>
<td>Lodine, Lodine XL</td>
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<td>Fenoprofen</td>
<td>Nalfon, Nalfon 200</td>
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<td>Flurbiprofen</td>
<td>Ansaid</td>
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<tr>
<td>Ibuprofen</td>
<td>Motrin, Tab-Profen, Vicoprofen* (combined with hydrocodone), Combunox (combined with oxycodone)</td>
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<td>Indomethacin</td>
<td>Indocin, Indocin SR, Indo-Lemmon, Indomethagan</td>
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<td>Ketorolac</td>
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<td>Nabumetone</td>
<td>Relafen</td>
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<tr>
<td>Naproxen</td>
<td>Naprosyn, Anaprox, Anaprox DS, EC-Naprosyn, Naprelan, Naprapac (copackaged with lansoprazole)</td>
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<td>Tolmetin</td>
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*Vicoprofen contains the same dose of ibuprofen as over-the-counter (OTC) NSAIDS, and is usually used for less than 10 days to treat pain. The OTC NSAID label warns that long term continuous use may increase the risk of heart attack or stroke.*
**IBU**
ibu tablet

### Product Information

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### Active Ingredient/Active Moiety

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### Inactive Ingredients

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CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)
HYDROXYPROPYL METHYLCELLULOSE (UNII: 3NXW29V3WO)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

Product Characteristics

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Marketing Information

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Labeler - DIRECT RX (079254320)
Registrant - DIRECT RX (079254320)

Establishment

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</tbody>
</table>

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