



Non Printing Colour

RD/PD/003/F-08/R0

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- **Other side effects of NSAIDs include:** stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness.

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

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

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

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

If you take too much of your NSAID, call your healthcare provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider or pharmacist about NSAIDs.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or contact Strides Pharma Inc. at 1-877-244-9825 or go to www.strides.com

Other information about Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

- Aspirin is an NSAID 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 NSAIDs 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.

General information about the safe and effective use of NSAIDs
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NSAIDs for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about NSAIDs, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about NSAIDs that is written for health professionals. For more information, call Strides at 1-877-244-9825.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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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.

- 1. Cardiovascular Thrombotic Events**
Advise patients to be alert for the symptoms of cardiovascular thrombotic events, including chest pain, shortness of breath, weakness, or slurring of speech, and to report any of these symptoms to their healthcare provider immediately (see **WARNINGS**).
- 2. Ibuprofen oral suspension, like other NSAIDs, can cause GI discomfort and, rarely, serious GI side effects, such as ulcers and bleeding, which may result in hospitalization or even death. Although serious GI tract ulcerations and bleeding can occur without warning symptoms, patients should be alert for signs and symptoms of ulcerations and bleeding, and should ask for medical advice when observing any indicative sign 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**).**
- 3. Serious Skin Reactions, including DRESS**
Advise patients to stop taking ibuprofen oral suspension immediately if they develop any type of rash or fever and to contact their healthcare provider as soon as possible (see **WARNINGS**).
- 4. Heart Failure and Edema**
Advise patients to be alert for the symptoms of congestive heart failure including shortness of breath, unexplained weight gain, or edema and to contact their healthcare provider if such symptoms occur (see **WARNINGS**).
- 5. 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.**
- 6. 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**).**
- 7. Fetal Toxicity**
Inform pregnant women to avoid use of ibuprofen oral suspension and other NSAIDs starting at 30 weeks gestation because of the risk of the premature closing of the fetal ductus arteriosus. If treatment with ibuprofen oral suspension is needed for a pregnant woman between about 20 to 30 weeks gestation, advise her that she may need to be monitored for oligohydramnios, if treatment continues for longer than 48 hours (see **WARNINGS, Fetal Toxicity, PRECAUTIONS, Pregnancy**).

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 a 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 if abnormal liver tests persist or worsen, ibuprofen oral suspension 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

Pharmacodynamic studies have demonstrated interference with the antiplatelet activity of aspirin when ibuprofen 400 mg, given three times daily, is administered with entericoated low-dose aspirin. The interaction exists even following a once-daily regimen of ibuprofen 400 mg, particularly when ibuprofen is dosed prior to aspirin. The interaction is alleviated if immediate-release low-dose aspirin is dosed at least 2 hours prior to a once-daily regimen of ibuprofen; however, this finding cannot be extended to entericoated low-dose aspirin (see **CLINICAL PHARMACOLOGY- Pharmacodynamics**). Because there may be an increased risk of cardiovascular events due to the interference of ibuprofen with the antiplatelet effect of aspirin, for patients taking low-dose aspirin for cardioprotection who require analgesics, consider use of an NSAID that does not interfere with the antiplatelet effect of aspirin, or non-NSAID analgesics, where appropriate.

As with other NSAIDs, concomitant administration of ibuprofen and aspirin is not generally recommended because of the potential of increased adverse effects.

Diuretics
Clinical studies, as well as post marketing observations, have shown that ibuprofen oral suspension can reduce the natriuretic effect of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with NSAIDs, the patient should be observed closely for signs of renal failure (see **WARNINGS, Renal Effects**), as well as to assure diuretic efficacy.

Lithium

Ibuprofen produced an elevation of plasma lithium levels and a reduction 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 this period of concomitant drug administration. This effect has been attributed to inhibition of renal prostaglandin synthesis by ibuprofen. Thus, when ibuprofen and lithium are administered concurrently, subjects should be observed carefully for signs of lithium toxicity. (Read circulars for lithium preparation before use of such concurrent therapy.)

Methotrexate

NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This may indicate that they could enhance the toxicity of methotrexate.

Warfarin

Several short-term controlled studies failed to show that ibuprofen significantly affected prothrombin times or a variety of other clotting factors when administered to individuals on warfarin-type anticoagulants. However, because bleeding has been reported when ibuprofen and other NSAIDs have been administered to patients on warfarin-type anticoagulants, the physician should be cautious when administering ibuprofen 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.

Pregnancy

Risk Summary

Use of NSAIDs, including ibuprofen oral suspension, can cause premature closure of the fetal ductus arteriosus and fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, limit dose and duration of ibuprofen oral suspension use between about 20 and 30 weeks of gestation, and avoid ibuprofen oral suspension use at about 30 weeks of gestation and later in pregnancy (see **WARNINGS: Fetal Toxicity**).

Premature Closure of Fetal Ductus Arteriosus

Use of NSAIDs, including ibuprofen oral suspension, at about 30 weeks gestation or later in pregnancy increases the risk of premature closure of the fetal ductus arteriosus.

Oligohydramnios/Neonatal Renal Impairment

Use of NSAIDs at about 20 weeks gestation or later in pregnancy has been associated with cases of fetal renal dysfunction leading to oligohydramnios, and in some cases, neonatal renal impairment.

Data from observational studies regarding other potential embryo fetal risks of NSAID use in women in the first or second trimesters of pregnancy are inconclusive. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively. Animal 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. Based on animal data, prostaglandins have been shown to have an important role in endometrial vascular permeability, blastocyst implantation, and decidualization. In animal studies, administration of prostaglandin synthesis inhibitors such as ibuprofen, resulted in increased pre- and post-implantation loss. Prostaglandins also have been shown to have an important role in fetal kidney development. In published animal studies, prostaglandin synthesis inhibitors have been reported to impair kidney development when administered at clinically relevant doses.

The estimated background risk of major birth defects and miscarriage for the indicated population(s) is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Premature Closure of Fetal Ductus Arteriosus:

Avoid use of NSAIDs in women at about 30 weeks gestation and later in pregnancy, because NSAIDs, including ibuprofen oral suspension, can cause premature closure of the fetal ductus arteriosus (see **WARNINGS: Fetal Toxicity**).

Oligohydramnios/Neonatal Renal Impairment

If an NSAID is necessary at about 20 weeks gestation or later in pregnancy, limit the use to the lowest effective dose and shortest duration possible. If ibuprofen oral suspension treatment extends beyond 48 hours, consider monitoring with ultrasound for oligohydramnios. If oligohydramnios occurs, discontinue ibuprofen oral suspension and follow up according to clinical practice (see **WARNINGS: Fetal Toxicity**).

Data

Human Data

There are no adequate, well-controlled studies in pregnant women. Ibuprofen should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Premature Closure of Fetal Ductus Arteriosus:

Published literature reports that the use of NSAIDs at about 30 weeks of gestation and later in pregnancy may cause premature closure of the fetal ductus arteriosus.

Oligohydramnios/Neonatal Renal Impairment:

Published studies and postmarketing reports describe maternal NSAID use at about 20 weeks gestation or later in pregnancy associated with fetal renal dysfunction leading to oligohydramnios, and in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. In many cases, but not all, the decrease in amniotic fluid was transient and reversible with cessation of the drug. There have been a limited number of case reports of maternal NSAID use and neonatal renal dysfunction without oligohydramnios, some of which were irreversible. Some cases of neonatal renal dysfunction required treatment with invasive procedures, such as exchange transfusion or dialysis.

Methodological limitations of these postmarketing studies and reports include lack of a control group; limited information regarding dose, duration, and timing of drug exposure; and concomitant use of other medications. These limitations preclude establishing a reliable estimate of the risk of adverse fetal and neonatal outcomes with maternal NSAID use. Because the published safety data on neonatal outcomes involved mostly preterm infants, the generalizability of certain reported risks to the full-term infant exposed to NSAIDs through maternal use is uncertain.

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 ibuprofen oral suspension on labor and delivery in pregnant women are unknown. Therefore, administration of ibuprofen oral suspension is not recommended during labor and delivery.

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 ibuprofen oral suspension, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of ibuprofen oral suspension in pediatric patients below the age of 6 months have not been established (see **CLINICAL PHARMACOLOGY - Clinical Studies**). Dosing of ibuprofen oral suspension in children 6 months or older should be guided by their body weight (see **DOSAGE AND ADMINISTRATION**).

Geriatric Use

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

ADVERSE REACTIONS

In patients taking ibuprofen or other NSAIDs, the most frequently reported adverse experiences occurring in approximately 1 to 10% of patients are: Abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, fluid retention, gastrointestinal experiences (including abdominal pain, bloating, constipation, diarrhea, dyspepsia, epigastric pain, flatulence, heartburn, nausea, vomiting), headaches, increased bleeding time, nervousness, pruritus, rashes (including maculopapular) and tinnitus.

Additional adverse experiences reported occasionally include:

Body as a whole	- fever, infection, sepsis
Cardiovascular system	- congestive heart failure in patients with marginal cardiac function, hypertension, tachycardia, syncope
Digestive system	- dry mouth, duodenitis, esophagitis, gastric or duodenal ulcer with bleeding and/or perforation, gastritis, gastrointestinal bleeding, glossitis, hematemesis, hepatitis, jaundice, melena, rectal bleeding
Hemic and lymphatic system	- ecchymosis, eosinophilia, leukopenia, purpura, stomatitis, thrombocytopenia
Metabolic and nutritional	- weight changes
Nervous system	- anxiety, asthenia, confusion, depression, dream abnormalities, drowsiness, insomnia, malaise, paresthesia, somnolence, tremors, vertigo
Respiratory system	- asthma, dyspnea
Skin and appendages	- alopecia, photosensitivity, sweat
Special senses	- blurred vision
Urogenital system	- cystitis, dysuria, hematuria, interstitial nephritis, oliguria/polyuria, proteinuria, acute renal failure in patients with pre-existing significantly impaired renal function

Other adverse reactions, which occur rarely are:

Body as a whole	- anaphylactic reactions, anaphylactoid reactions, appetite changes
Cardiovascular system	- arrhythmia, cerebrovascular accident, hypotension, myocardial infarction, palpitations, vasculitis
Digestive system	- eructation, gingival ulcer, hepatomegal syndrome, liver necrosis, liver failure, pancreatitis
Hemic and lymphatic system	- agranulocytosis, hemolytic anemia, aplastic anemia, lymphadenopathy, neutropenia, pancytopenia
Metabolic and nutritional	- hyperglycemia
Nervous system	- convulsions, coma, emotional lability, hallucinations, aseptic meningitis
Respiratory	- apnea, respiratory depression, pneumonia, rhinitis
Skin and appendages	- angioedema, toxic epidermal necrosis, erythema multiforme, exfoliative dermatitis, Stevens Johnson syndrome, fixed drug eruption (FDE), urticaria, vesiculobullous eruptions
Special senses	- amblyopia (blurred and/or diminished vision, scotomata and/or changes in color vision), conjunctivitis, dry eyes, hearing impairment
Urogenital	- azotemia, decreased creatinine clearance, glomerulitis, renal papillary necrosis, tubular necrosis

To report SUSPECTED ADVERSE REACTIONS, contact Strides Pharma Inc. at 1-877-244- 9825 or go to www.strides.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

OVERDOSAGE

The toxicity of ibuprofen overdose is dependent upon the amount of drug ingested and the time elapsed since ingestion, though individual response may vary, which makes it necessary to evaluate each case individually. Although uncommon, serious toxicity and death have been reported in the medical literature with ibuprofen overdose. The most frequently reported symptoms of ibuprofen overdose include abdominal pain, nausea, vomiting, lethargy and drowsiness. Other central nervous system symptoms include headache, tinnitus, CNS depression and seizures. Metabolic acidosis, coma, acute renal failure and apnea (primarily in very young children) may rarely occur. Cardiovascular toxicity, including hypotension, bradycardia, tachycardia and aortic fibrillation, also have been reported.

The treatment of acute ibuprofen overdose is primarily supportive. Management of hypotension, acidosis and gastrointestinal bleeding may be necessary. In cases of acute overdose, the stomach should be emptied through ipecac-induced emesis or lavage. Emesis is most effective if initiated within 30 minutes of ingestion. Orally administered activated charcoal may help in reducing the absorption and reabsorption of ibuprofen.

In children, the estimated amount of ibuprofen ingested per body weight may be helpful to predict the potential for development of toxicity although each case must be evaluated. Ingestion of less than 100 mg/kg is unlikely to produce toxicity. Children ingesting 100 to 200 mg/kg may be managed with induced emesis and a minimal observation time of four hours. Children ingesting 200 to 400 mg/kg of ibuprofen should have immediate gastric emptying and at least four hours observation in a health care facility. Children ingesting greater than 400 mg/kg require immediate medical referral, careful observation and appropriate supportive therapy. Ipecac-induced emesis is not recommended in overdoses greater than 400 mg/kg because of the risk for convulsions and the potential for aspiration of gastric contents.

In adult patients the history of the dose reportedly ingested does not appear to be predictive of toxicity. The need for referral and follow-up must be judged by the circumstances at the time of the overdose ingestion. Symptomatic adults should be carefully evaluated, observed and supported.

DOSAGE AND ADMINISTRATION

Carefully consider the potential benefits and risks of ibuprofen oral suspension and other treatment options before deciding to use ibuprofen oral suspension. 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 ibuprofen oral suspension, the dose and frequency should be adjusted to suit an individual patient's needs.

Pediatric Patients

Fever Reduction: For reduction of fever in children, 6 months up to 2 years of age, the dosage should be adjusted on the basis of the initial temperature level (see **CLINICAL PHARMACOLOGY**). The recommended dose is 5 mg/kg if the baseline temperature is less than 102.5°F, or 10 mg/kg if the baseline temperature is 102.5°F or greater. The duration of fever reduction is generally 6 to 8 hours. The recommended maximum daily dose is 40 mg/kg.

Analgesia: For relief of mild to moderate pain in children 6 months up to 2 years of age, the recommended dosage is 10 mg/kg, every 6 to 8 hours. The recommended maximum daily dose is 40 mg/kg. Doses should be given so as not to disturb the child's sleep pattern.

Juvenile Arthritis: The recommended dose is 30 to 40 mg/kg/day divided into three to four doses (see **Individualization of Dosage**). Patients with milder disease may be adequately treated with 20 mg/kg/day.

In patients with juvenile arthritis, doses above 50 mg/kg/day are not recommended because they have not been studied and doses exceeding the upper recommended dose of 40 mg/kg/day may increase the risk of causing serious adverse events. The therapeutic response may require from a few days to several weeks to be achieved. Once a clinical effect is obtained, the dosage should be lowered to the smallest dose of ibuprofen oral suspension needed to maintain adequate control of symptoms.

Pediatric patients receiving doses above 30 mg/kg/day or if abnormal liver function tests have occurred with previous NSAID treatments should be carefully followed for signs and symptoms of early liver dysfunction.

Adults

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

Rheumatoid Arthritis and Osteoarthritis: Suggested dosage: 1200 to 3200 mg daily (300 mg q.i.d. or 400 mg, 600 mg or 800 mg t.i.d. or q.i.d.). 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.

Individualization of Dosage: The dose of ibuprofen oral suspension should be tailored to each patient, and may be lowered or raised from the suggested doses depending on the severity of symptoms either at time of initiating drug therapy or as the patient responds or fails to respond.

One fever study showed that, after the initial dose of ibuprofen oral suspension, subsequent doses may be lowered and still provide adequate fever control.

In a situation when low fever would require the ibuprofen oral suspension 5 mg/kg dose in a child with pain, the dose that will effectively treat the predominant symptom should be chosen.

In chronic conditions, a therapeutic response to ibuprofen oral suspension therapy 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.

Patients with rheumatoid arthritis seem to require higher doses than do patients with osteoarthritis. The smallest dose of ibuprofen oral suspension that yields acceptable control should be employed.

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

HOW SUPPLIED

Ibuprofen Oral Suspension, USP 100 mg/5 mL

Pale yellow to orange color suspension with mixed berry flavor.
- Carton containing bottle of 4 fl oz (118 mL) - NDC 64380-997-03
- Bottles of One Pint (473 mL) - NDC 64380-997-04

Shake well before using. Store at 20°C to 25°C (68°F to 77°F). [see USP Controlled Room Temperature.]

Dispense in a well-closed container as defined in the USP.

Manufactured by:

Strides Pharma Science Limited
Bengaluru – 562106, India.

Distributed by:
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Bridgewater, NJ 08807.

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ARTWORK DETAIL LABEL

Product	Ibuprofen Oral Suspension, USP 100 mg/5 mL			
Buyer/Country	STRIDES PHARMA INC - US	Component	Outsert with Medication Guide	
Dimension	380 x 450 mm	Pack	----	
New Item Code	1052678	Old Item Code	1050966	
Colour Shades	BLACK	No. of Colours	1	

Change Control No.	PC-TSG/2025/052 - Record Number: 463027& PC-ODF/2025/408 - Record Number: 460262	Artwork Version	5.0
Design/Style	Front & Back Printing. Booklet Form. (Folded size: 36 x 35 mm). To be supplied in the folded Booklet form with pasting.		
Substrate	40 GSM Bible Paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartanator Requirements	NA		
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.			

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