# PARACETAMOL IBUPROFEN
## (as sodium dihydrate)

**UNIPHARM**

# ALAXAN® XTRA

**325 mg/200 mg Film-Coated Tablet**
**Analgesic / Antipyretic / Non-Steroidal Anti-Inflammatory Drug (NSAID)**

**FORMULATION**
Each film-coated tablet contains:

| | |
|---|---|
| Paracetamol | 325 mg |
| Ibuprofen | 200 mg |
| equivalent to 256.23 mg Ibuprofen as sodium dihydrate) | |

**PRODUCT DESCRIPTION**
Paracetamol or Ibuprofen (as sodium dihydrate) (Alaxan® XTRA) 325 mg / 200 mg Film-Coated Tablet is a peach, elliptical shaped, biconvex, film-coated tablet, plain on both sides.

**WHAT IS IN THE MEDICINE**
Alaxan® XTRA is a combination of Ibuprofen and paracetamol. Ibuprofen belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). Like other NSAIDs, it has anti-inflammatory properties and helps to relieve pain, reduce fever and lower high blood pressure. Paracetamol is a fever reducer and pain reliever.
Ibuprofen and paracetamol are paracetamol has a synergistic effect, i.e., they work together to improve your health. Ibuprofen offers anti-inflammatory activity of the ibuprofen + paracetamol combination is greater, and is able to relieve pain better at lower doses as a individual ingredients. Ibuprofen is a fast-acting formulation of sodium salt (SyncTech), a novel innovative fixed-dose combination tablet that dissolved ibuprofen sodium dihydrate and paracetamol. SyncTech combines the two approaches that are well established to result in faster onset of pain relief, which is associated with better overall pain relief, a greater proportion of subjects with pain relief, and longer duration.

**STRENGTH OF THE MEDICINE**
See Formulation

**WHAT IS THE MEDICINE USED FOR?**
- For the relief of mild to moderately severe pain of musculoskeletal origin such as muscle pain (myalgia), arthritis, rheumatism, spine, strain, bursitis (inflammation of the fluid sac between the joints), tendinitis (inflammation of tendons), sciatica, sprains, and stiff neck.
- For the relief of tension headache, dysmenorrhea, toothache, pain after tooth extraction and minor surgical operations.

**HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?**
Like other NSAIDs, the lowest effective dose should be used for the shortest possible time. After observing the response to initial therapy with this product, the dose and frequency should be adjusted to suit individual patient needs.
Adults and children 12 years and older: 1 tablet every 6 hours as needed, or as directed by a doctor.
Adults and children 12 years and older: 1 tablet every 8 hours as needed, or as directed by a doctor.
- Do not exceed 3 tablets per 24 hour period.
- Do not take for more than 10 days unless directed by a doctor.
- Not recommended for children below 12 years old.

**WHEN SHOULD YOU NOT TAKE THIS MEDICINE?**
Do not take this medicine if you are:
- Allergic to paracetamol, ibuprofen, aspirin other NSAIDs, or to other ingredients in the product
- Suffering from peptic ulcer or bleeding problems
- Taking aspirin or other NSAIDs
- Bronchospasm (constriction of air passages of the lungs), worsening of asthma, angioedema (rapid swelling that occurs in the tissue just below the surface of the skin), nasal polyps or allergic-type reactions (e.g., skin rashes) after taking aspirin or other NSAIDs
- Severe liver disease, severe kidney disease, severe heart failure or more distinct episodes of proven ulceration or bleeding) or other gastrointestinal problems (e.g., peptic ulcer, Crohn's disease)
- Severe heart disease (NYHA Class IV)
- Severe liver disease
- Severe kidney disease (creatinine clearance less than 30 ml/min)
- Conditions involving an increased tendency to bleeding, including Dengue fever of any stage
- Dehydrated (significant fluid loss due to vomiting, diarrhea or lack of fluids
- Severe uncontrolled heart failure, or at risk of it
- Systemic Lupus Erythematosus (SLE)
- During the last 3 months of pregnancy
- Breastfeeding women, because of the potential for serious undesirable effects in breastfed infants
- Right before or after heart surgery

**UNDESIRABLE EFFECTS**
Ibuprofen
*Gastrointestinal effects:* Common effects of Ibuprofen involve the gastrointestinal tract and include dyspepsia (indigestion), heartburn, nausea, vomiting, loss of appetite, diarrhea, gas (flatulence), bowel movement, constipation (decreased number of or difficulty making bowel movements), stomach pain, cramps, and bloating. Less frequently, the mouth will become ulcerated, gastritis (inflammation of the stomach) and jaundice (yellowing of skin and eyes).
*Cardiac effects and infectious:* Abscess, conjunctivitis (irritation and redness of the thin membrane covering the eye), infection, pustule, sepsis (severe illness in which the bloodstream is overwhelmed by bacteria), skin infection.
*Blood and lymphatic system disorders:* Blood disorders include reduction in the number of white blood cells), anemia (reduce in red blood cells), aplastic anemia (severe reduction in blood cells which can cause weakness, bruising or make infections more likely), bone marrow depression (reduce in blood cells), eosinophilia (increase in a type of white blood cell), hemolytic anemia (destruction of red blood cells), hemolytic anemia (destruction of red blood cells), inhibition of platelet aggregation, leukopenia (low white blood cell count), neutropenia (abnormally low white blood cells), pancytopenia (abnormal decrease in the levels of all types of blood cells), pure red cells aplasia, thrombocytopenia (low platelet count).
*Immune system disorders:* Allergic rhinitis, angioedema (swelling of the face, tongue or throat), anaphylactoid reaction or anaphylaxis (severe allergic reaction), asthma (difficulty breathing), bronchospasm (constriction of airways), chest tightness, cardiovascular accident (stroke), cardiac arrest, hypotension (abnormally low blood pressure), shock, vasospasm (constriction of blood vessels), vasculitis (inflammation of the blood vessels), myocardial infarction (heart attack), pancytopenia (abnormal decrease in the levels of all types of blood cells), pure red cells aplasia, thrombocytopenia (low platelet count).
*Immune system disorders:* Allergic rhinitis, angioedema (swelling of the face, tongue or throat), anaphylactoid reaction or anaphylaxis (severe allergic reaction), asthma (difficulty breathing), bronchospasm (constriction of airways), chest tightness, cardiovascular accident (stroke), cardiac arrest, hypotension (allergic reaction) (severe allergic reaction to certain medications used to treat certain medical conditions), swelling of lymph nodes, vasospasm (constriction of blood vessels).
*Metabolism and nutrition disorders:* Decrease in the number of platelets in the blood, decreased appetite, edema (fluid retention), hyperkalemia (increased blood level of potassium), hypoglycemia (low blood sugar), hyponatremia (decreased level of sodium), water retention.
*Psychiatric disorders:* Aggression, anxiety, confusion, confusional state, depression (feelings of sickness, worthlessness, thoughts of suicide or death), disorientation, insomnia (difficulty sleeping), irritability (feelings that are not there while a person is awake), mood disorder (mania), nervousness, psychotic disorders.
*Nervous system disorders:* Aseptic meningitis (inflammation of the membrane that covers the brain and spinal cord), cerebrovascular accident (stroke), coma, convulsion, dysgeusia (trouble taste), dizziness, encephalitis, hemiparesthesia (inflammation of the membrane which keep brain and spinal cord safe), hypoesthesia (reduced sensitivity to touch), intracranial hypertension (increased pressure in the fluid around the brain), paresthesia (abnormal sensations, commonly described as pins and needles), peripheral neuropathy (damage to the nerves that carry signals to and from the brain and spinal cord), seizure (fainting of spinning or shifting).
*Eye disorders:* Blurred vision, diplopia (loss of visual sharpness), blindness, blurred vision, cataracts, decreased visual acuity, dry eye, dyschromatopsia (change in color vision), eye pain, eye pruritus, optic neuritis (inflammation of the optic nerve), scotoma (defect in visual field), visual impairment.
*Ear and labyrinth disorders:* Decreased hearing, hearing impairment, tinnitus (ringing in the ears).
*Cardiac disorders:* Arrhythmia (irregular heartbeat), heart failure, myocardial infarction (heart attack), palpitations (feelings of breath or ankle swelling), tachycardia (rapid heart beat), cardiac failure (failure of the heart resulting in fluid build-up in the lungs), cardiomyopathy (disease of the heart muscle), myocardial infarction (heart attack), pericarditis (inflammation of the pericardium), tachycardia (rapid heart beat), vasodilatation (widening of blood vessels).
*Vascular disorders:* Bulbus leukocytoclastic vasculitis, epistaxis (nosebleed), flushing, hemorrhage (bleeding), Henoch-Schönlein purpura (inflammation of small blood vessels), hypertension (high blood pressure), hypotension (decreased blood flow in the body), shock, thrombosis.
*Breathing, thoracic, and mediastinal disorders:* Asthma, dyspnea (difficulty in breathing), rhinitis or rhinorrhea (runny or stuffy nose), bronchospasm.
*Gastrointestinal disorders:* Dry mouth, duodenal ulcer (ulcer in the lining of an area of the small intestine called duodenum), dysphagia (difficulty in swallowing), esophagitis (inflammation of a tube that carries food from the throat to the stomach), exacerbation of Crohn's disease (serious inflammation to any part of the gastrointestinal tract), gastric hemorrhage (stomach bleeding), gastric ulcer (ulcer in the lining of the stomach), gastritis (inflammation of the stomach), gastrointestinal perforation (hole in the digestive tract), gastrointestinal perforation (hole in the digestive tract), gingival ulceration (ulcers in the gums), hematemesis (blood in vomit), melena (black, tarry stools), nausea, nonspecific gastrointestinal bleeding, pancreatitis (inflammation of the pancreas), stomatitis (inflammation of the mouth), ulcerative colitis (ulcers in the lining of the large intestine), vomiting.
*Hepatic and hepatobiliary disorders:* Abnormal liver function, cholestasis (reduced flow of bile), hepatitis (inflammation of the liver), jaundice (yellowing of skin and eyes), liver failure, liver disorder.
*Skin and subcutaneous tissue disorders:* Acne, alopecia (hair loss), acute generalized exanthematous pustulosis (rare skin reaction characterized by numerous small pustules), angioedema (swelling of the face, tongue or throat), bullous eruptions, dermatitis, exfoliative dermatitis, erythema multiforme (skin reaction with flat or raised red patches), erythema nodosum (painful red nodules on the skin), fixed drug eruption (recurrent skin rash in the same place caused by a reaction to a medicine), hypersensitivity (allergic reaction), lichenoid keratosis (a type of skin rash), photosensitivity (abnormally heavy bleeding during menstruation), pruritus (itching), rash, skin irritation, skin lesion, skin peeling, skin reddening, skin swelling, Stevens-Johnson syndrome (potentially life-threatening condition in which the skin and mucous membranes of the body become very ill), toxic epidermal necrolysis (severe skin and mucous membrane disease), urticaria (hives).
*Musculoskeletal and connective tissue disorders:* Joint swelling, neck stiffness, soft tissue disorder, systemic lupus erythematosus (allergic condition which affects many parts of the body), muscle cramps.
*Renal and urinary disorders:* Acute kidney injury, acute tubular necrosis, azotemia (an excess of urea or other nitrogenous wastes in the blood), cystitis (inflammation of the bladder), glomerular disease, hematuria (blood in urine), hepatorenal syndrome (liver and kidney failure), nephrotoxicity (poisonous to the kidneys), nephrotic syndrome, oliguria (decreased amount of urine), polyuria (excessive urination), proteinuria (more protein leaking in the urine than usual), renal failure, renal impairment (loss of the function of the kidneys in which all or part of the renal physiologic (kidney) tasks are lost), tubulointerstitial nephritis (inflammation affecting the tubules of the kidneys), urine abnormality.
*Reproductive system and breast disorders:* Abnormal sperm, gynecomastia (breast enlargement in males), menorrhagia (abnormally heavy bleeding during menstruation).
*General disorders and administration site conditions:* Chills, fatigue, influenza-like illness, leg swelling, malaise (feeling sick), pyrexia (fever), swelling, thirst.
*Investigations:* Abnormal liver function, decreases in creatinine clearance, glomerular filtration rate, hemoglobin, hematocrit, serum blood urea nitrogen, liver enzyme abnormalities, alanine aminotransferase increased, aspartate aminotransferase, bilirubin, serum urea, serum uric acid, positive coulombic blood test, prolonged bleeding time
*Injury, poisoning and procedural complications:* Contusion, excoriation, sunburn, toxic epidermal necrolysis (serious illness with blistering of the skin)

Paracetamol
*Immune system disorders:* Allergic reactions (some allergic-type reactions), angioedema (swelling of the face, tongue or throat), anaphylactoid reaction or anaphylaxis (severe allergic reaction), bronchospasm (constriction of airways), hypotension (abnormally low blood pressure), urticaria (hives), swelling around the eyes, urticaria (hives).
*Blood and lymphatic system disorders:* Hypercifibrinemia (increased chlorine on the blood), hypercitrulinemia (increased uric acid in the blood), loss of epithelial, sudden weight loss
*Eye and labyrinth disorders:* Blurred vision
*Cardiac disorders:* Myocardial infarction (heart attack), tachycardia (fast heartbeat with regular rhythm)
*Ear and labyrinth disorders:* Tinnitus (ringing in the ears)
*Vascular disorders:* Hypertension (high blood pressure), vasodilatation (widening of blood vessels), vasospasm (constriction of blood vessels)
*Gastrointestinal disorders:* Abdominal pain, constipation, diarrhea, dyspepsia (indigestion), nausea, vomiting
*Hepatobiliary disorders:* Liver dysfunction, liver injury, yellowing of eyes and skin
*Renal and urinary disorders:* Dysuria
*Investigations:* Decrease in serum phosphorus, increase in alkaline phosphatase, serum sodium increases in alanine aminotransferase, ammonia, bilirubin, serum albumin phosphorus, serum glucose
*Injury poisoning and procedural complications:* Overdose
Ibuprofen + Paracetamol
*Skin and subcutaneous tissue disorders:* Conjunctivitis (irritation and redness of the thin membrane covering the eye)
*Blood and lymphatic system disorders:* Agranulocytosis (severe reduction in the number of white blood cells), anemia (reduce in red blood cells), aplastic anemia (severe reduction in blood cells which can cause weakness, bruising or make infections more likely), eosinophilia (abnormally high levels of eosinophils), blood disorders, hemolytic anemia (anemia due to the destruction of red blood cells), hemolytic anemia (anemia due to the destruction of red blood cells), leukopenia (low white blood cell count), neutropenia (abnormally low white blood cells), pancytopenia (abnormal decrease in the levels of all types of blood cells), pure red cells aplasia, thrombocytopenia (low platelet count).
*Immune system disorders:* Allergic reactions (symptoms include hives, angioedema (swelling of the face, tongue or throat), difficult breathing, asthma or severe allergic reaction), asthma (difficulty breathing), bronchospasm (constriction of airways), hypotension (abnormally low blood pressure), shock (allergic reaction to certain medications used to treat certain medical conditions), swelling of lymph nodes
*Nervous system disorders:* Aseptic meningitis (inflammation of the membrane that covers the brain and spinal cord), cerebrovascular accident (stroke), coma, dysgeusia (trouble taste), dizziness, headache, paresthesia (tingling or numbness of hands or feet), toxic optic neuropathy (visual dizziness due to a toxic reaction), toxic amblyopia (blurred vision), vertigo (feeling of spinning or shifting)
*Eye disorders:* Amblyopia (loss of visual sharpness), blurred vision, cataracts, dyschromatopsia (change in color vision), optic neuritis (inflammation of the optic nerve), scotoma (defect in visual field), visual impairment
*Ear and labyrinth disorders:* Deafness, hearing impairment, tinnitus (ringing in the ears)
*Cardiac disorders:* Arrhythmia (irregular heartbeat), heart failure, myocardial infarction (heart attack), sinus bradycardia (slow heartbeat with regular rhythm), tachycardia (fast heartbeat with regular rhythm)
*Vascular disorders:* Epistaxis (nosebleed), hemorrhage (bleeding), Henoch-Schönlein vasculitis, hypertension (high blood pressure), hypotension (decreased blood flow in the body), shock, thrombosis (blood clot in the body), vasculitis
*Gastrointestinal disorders:* Bleeding, constipation (decreased number of or difficulty making bowel movements), diarrhea (frequent loose bowel movements), dry mouth, dyspepsia (indigestion), gastric hemorrhage (stomach bleeding), gastrointestinal perforation (hole in the digestive tract), hematemesis (vomiting blood), melena (black, tarry stools), nausea, nonspecific gastrointestinal bleeding, pancreatitis (inflammation of the pancreas), stomatitis (inflammation of the mouth), ulcerative colitis (ulcers in the lining of the large intestine), vomiting
*Hepatic and hepatobiliary disorders:* Abnormal liver function, cholestasis (reduced flow of bile), hepatitis (inflammation of the liver), jaundice (yellowing of skin and eyes), liver failure, liver disorder
*Musculoskeletal and connective tissue disorders:* Neck stiffness, systemic lupus erythematosus (allergic condition which causes joint pain, skin rashes, and organ damage)
*General disorders and administration site conditions:* Chills, excessive sweating, fatigue, influenza-like illness, malaise (feeling sick), pyrexia (fever)
*Investigations:* Abnormal liver function, decreased hematocrit, hemoglobin, increases in alanine aminotransferase, aspartate aminotransferase, blood urea nitrogen, creatinine, liver enzyme abnormalities, liver enzymes, platelet counts, prolonged coagulation time, serum potassium, serum uric acid

**WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?**
**Aspirin:** Ibuprofen may interfere with the anti-platelet activity of aspirin. Long-term use of Ibuprofen may cause low-dose aspirin to be less effective for cardiovascular protection. Do not take Alaxan® XTRA if you are taking aspirin and/or other medicines that are used to treat pain.
**Other NSAIDs:** Phenylbutazone, indomethacin, salicylates (e.g., aspirin), and other NSAIDs (e.g., meflenamic acid, naproxen, diclofenac, etoricoxib), celecoxib, parecoxib, lumiracoxib, rofecoxib, valdecoxib, etoricoxib, etodolac, etodolac, sulindac, and aspirin always increase bleeding risks, excepting potentially high levels of eosinophilia; blood disorders, hemolytic anemia (anemia due to the destruction of red blood cells), hepatitis (inflammation of the liver), jaundice (yellowing of skin and eyes), liver function abnormality, nephrotoxicity (poisonous to the kidneys).
**Other Medicines Containing Paracetamol:** Do not take other medicines containing paracetamol (prescription or nonprescription) if you are not sure whether a medicine contains paracetamol, ask a doctor.
**Alcohol:** Alcohol intake increases the risk of stomach irritation and paracetamol-induced liver damage.
**Aminoglycosides:** NSAIDs, such as ibuprofen, increase aminoglycoside toxicity by decreasing the excretion of aminoglycosid antibiotics (a type of antibiotic medicine).
**Antacids and Adsorbents:** Absorption of NSAIDs with drugs used for hyperkalemia (e.g., captopril, enalapril, losartan, spironolactone, furosemide) may increase the risk of acute renal failure and potassium (potassium in blood) levels. Antacids may also reduce the absorption of NSAIDs.
**Blood Thinning Medicines (Anticoagulants):** NSAIDs may enhance the effects of these agents (e.g., warfarin). The use of NSAIDs and anticoagulants may increase the risk of gastrointestinal bleeding. Ibuprofen may interfere with the platelet activity of warfarin. Ibuprofen may increase International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding, may be observed when using ibuprofen or paracetamol and warfarin at the same time.
**Cardiac Glycosides:** NSAIDs may worsen heart failure, reduce kidney function and increase blood levels of cardiac glycosides (e.g. digoxin).
**Chloroquine:** Concomitant may increase risk of gastrointestinal toxicity.
**Colesapin and Tacrolimus:** The risk of kidney damage may be increased when these medicines are taken with ibuprofen. In addition, NSAIDs may also increase the toxicity of tacrolimus.
**Corticosteroids, Selective Serotonin-Reuptake Inhibitors (SSRIs), and Anti-platelet Agents:** The use of ibuprofen with these drugs may increase the risk of stomach ulceration or bleeding.
**Digoxin Intake:** The risk of bleeding may be increased when ibuprofen is taken with Ginkgo biloba.
**Diuretics:** Ibuprofen may reduce the effect of diuretics (water pills).
**Lithium and Methotrexate:** Ibuprofen may increase the blood levels of these medicines, thus increasing the risk of toxicity.
**Medicines affecting liver enzymes:** Medicines that inhibit the enzyme responsible for the metabolism of ibuprofen (e.g., ivorixocaxia, fluvoxamine) may increase the risk of toxicity. Medicines that induce the enzyme responsible for the metabolism of ibuprofen (e.g. the metabolism of paracetamol such as medicines for convulsion (e.g., phenobarbital, phenytoin, carbamazepine, barbiturates) may reduce the effect of paracetamol and increase the toxicity of paracetamol, such as liver damage.
**Medicines that lower blood sugar (for diabetes):** Ibuprofen may increase the effect of insulin and other medicines used to treat diabetes (sulfonylurea and a biguanide) (Glucophage).
**Medicines used to treat depression:** These medicines may increase the risk of bleeding associated with NSAIDs.
**Medicines used to treat high blood pressure:** NSAIDs may increase the adverse effect of these medicines, including the risk of gastrointestinal ulcers and kidney toxicity.
**Metoclopramide, Domperidone and Cisapride:** The absorption of paracetamol may be accelerated by metoclopramide or domperidone and cisapride. Ibuprofen may be absorbed more slowly in the gastrointestinal tract may also be reduced by cholestyramine.
**Mifepristone:** NSAIDs such as ibuprofen can reduce the effect of mifepristone.
**Phenothiazines:** Phenothiazines (medicines for serious mental and emotional disorder) may increase the risk of severe hypothermia (abnormally low body temperature) and kidney dysfunction.
**Probenecid:** Taken the excreted of ibuprofen, thus increasing the risk of ibuprofen toxicity. Probenecid may also affect the excretion and concentrations of paracetamol in the blood.
**Sorbitol Solution:** The risk of diarrhea is increased when associated with quinolone antibiotics may increase with NSAID use.
**Zidovudine:** An increased risk of blood problems such as bleeding into a joint (hemarthrosis) and bruising (hematoma) may result when ibuprofen is taken at the same time.

**Tell your doctor if you are taking other medicines (especially other paracetamol-containing medicines), including vitamins, supplements, and herbal medicines.**

**WHAT SHOULD YOU DO IF YOU MISS A DOSE?**
If you missed a dose, take the next dose as soon as you remember it still needed for pain and/or fever or anti-inflammatory effect and then subsequent doses every 6 hours.
Do not double the dose to make up for the missed dose. Do not exceed the maximum dose in 24 hours.

**HOW SHOULD YOU STORE THE MEDICINE?**
Keep the product out of sight and reach of children.
Store at temperature below 30°C.

**SIGNS AND SYMPTOMS OF OVERDOSAGE**
The most frequently reported symptoms of Ibuprofen overdose include abdominal pain, nausea, vomiting, fatigue and drowsiness. Other symptoms include headache, tinnitus (ringing in the ears), and loss of consciousness. Other symptoms of Ibuprofen overdose include (excessive acidity of the blood), coma, nystagmus (rapid, jerky involuntary movements of the eye), hypothermia (low body temperature), hypotension (low blood pressure), cardiovascular collapse, renal failure, liver dysfunction, convulsions, respiratory depression, cyanosis (bluish-purple discoloration of the skin), respiratory arrest and respiratory system may rarely occur. Cardiovascular reactions, such as hypotension (decreased blood pressure), bradycardia (slow heart rate), tachycardia (fast heart rate), and atrial fibrillation (irregular heart beat) may also occur. Symptoms of the carriers of the (heart), have also been reported. Kidney failure and liver damage are possible in cases of significant overdose. Exacerbation of asthma is possible in asthmatics.
Overdosage of paracetamol usually involves the risk of liver damage. Symptoms of overdose are:
1. Reduced or loss of appetite, nausea, vomiting, malaise (a general feeling of being unwell), and excessive sweating.
2. Right upper quadrant pain or tenderness in the liver, enlargement which may be accompanied by additional discomfort of "feeling full" elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time, and occasionally decreased urine output.
3. Liver failure, which may be fatal, may develop over the following days. Metabolic acidosis (excessive acidity in the blood) is likely to be present in (e.g., jaundice, hypoglycemia, coagulation disorders, and hypotonicity), and possibly kidney failure and cardiomyopathy (disorder of the heart muscle) may develop.

Recovery or progression to total complete liver failure
Metabolic acidosis (excessive acid in the body), encephalopathy (disorder brain function), coma, and death may also occur. Clinical and laboratory evidence of hepatic toxicity may not be apparent 48 to 72 hours post-ingestion, and reach a maximum after 4 to 6 days.

**WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?**
If you have taken more than the recommended dosage, consult a doctor or contact a poison control center right away, even if you seem well as there is a risk of delayed serious damage to your liver. Do not take more than the recommended dosage.

**CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE**
- Ibuprofen may make you feel dizzy or affect your ability to do things, such as, do not drive, operate machinery or do anything that requires you to be alert.
- **Allergy Alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
  - Hives (elevated, whitish or reddish patches on the skin with severe itching or pinking sensations)
  - Tight chest, difficulty breathing, wheezing, asthma (sudden wheezing or shortness of breath), or bronchospasm
  - Swelling of the face, lips, or tongue, which may cause difficulty in swallowing and breathing
  - Unusual hoarseness
  - Itching and rash
  - Blisters
  - Stomach ache, fever, chills, nausea and vomiting
  - Fainting
- **Stomach Bleeding Warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
  - Are age 60 years or older
  - Have had stomach ulcers or bleeding problems
  - Take a blood thinning (anticoagulant) or steroid medicine
  - Take other medicines containing prescription or nonprescription NSAIDs (aspirin, naproxen, or others)
  - Have 3 or more alcoholic drinks everyday while using this product
  - Take more than the directed dosage
  - You regularly drink alcohol
  - You have a connective tissue disease (autoimmune diseases affecting connective tissue like systemic lupus erythematosus)
  - You are hypertension, a blood thinning medicine
  - You are having problems or serious side effects from taking pain relievers or fever reducers
  - You are over 60 years old, pregnant or in the last trimester of pregnancy
  - You are taking other medicines
  - You are under a doctor's care for any serious condition
  - You are trying to become pregnant, NSAIDs may impair fertility in women. This effect is reversible upon stopping the medicine.

**Do not use paracetamol if you are or if you think you are:**
- You experience any of the following signs of stomach bleeding:
  - Feel faint
  - Vomit blood
  - Have bloody or black stools
  - Have stomach pain that does not get better
  - Have severe stomach pain
  - Difficulties in breathing or unexplained wheezing
  - Dizziness or faster heartbeat
- **Liver and Kidney Warning:** Ibuprofen may cause liver or kidney damage.
  - An adult or child over 12 years old takes more than 4 g of paracetamol in 24 hours, which is the maximum daily amount
  - Taken with other medicines containing paracetamol (or acetaminophen)
  - An adult has 3 or more alcoholic drinks everyday while using this product
  - Take a dose of heart attack or stroke may increase if you use more than directed or for longer than directed.
  - This medicine may mask the usual signs of infection.
  - Do not use after the expiry date (EXP).

**WHEN SHOULD YOU CONSULT YOUR DOCTOR?**
**Ask a doctor before use if:**
- You have allergies to any other medicines, including aspirin or other NSAIDs
- Stomach bleeding warning applies to you if you have ever had any ulcers or have other bleeding problems
- You have heart problems, previous stroke, or might be at risk of these conditions (e.g., high blood pressure, high cholesterol, diabetes, or if you are a smoker
- You have chest pain or have had coronary artery bypass surgery, or peripheral artery disease (poor circulation in the legs of feet due to narrowed or blocked blood vessels)
- You have a tropical condition such as Dengue, such as heartburn. Crohn's disease (inflammation of the digestive system) or ulcerative colitis (ulcers in the lining of the rectum and colon)
- You have asthma, chronic runny nose, sinus infections, nose polyps, or allergic reactions that may include shortness of breath
- You are taking a diuretic or are a diet restricting your salt intake
- You are planning to have surgery
- You are being treated for dehydration, or has a severe infection
- You regularly drink alcohol
- You have a connective tissue disease (autoimmune diseases affecting connective tissue like systemic lupus erythematosus)
- You are hypertension, a blood thinning medicine
- You are having problems or serious side effects from taking pain relievers or fever reducers
- You are over 60 years old, pregnant or in the last trimester of pregnancy
- You are taking other medicines
- You are under a doctor's care for any serious condition
- You are trying to become pregnant, NSAIDs may impair fertility in women. This effect is reversible upon stopping the medicine.

**Ask a doctor before use if you are breastfeeding**, and a doctor before use. It is especially important not to use Ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. It is also not recommended to take this medicine during breastfeeding.

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND UNILAB, Inc. Pharmacovigilance at +63 (2) 8-8-645-22 or 1-800-10-UNILAB (1-800-10-8645-22) or 1-800-10-UNILAB (1-800-10-8645-22) or pharmacovigilance@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

**AVAILABILITY:** Laminated Blister Foil x 4's (Box of 10's and 12's)
**Date of Revision of Patient Information Leaflet:** June 2026
**Date of First Authorization:** 09 July 2024

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