

IBUPROFEN+PARACETAMOL

ALAXAN[®] 200 mg / 325 mg TABLET ALAXAN[®] FR 200 mg / 325 mg CAPSULE

Non-steroidal Anti-inflammatory Drug / Analgesic-Antipyretic

FORMULATION

Each tablet/capsule contains: Ibuprofen200 mg
Paracetamol 325 mg

PRODUCT DESCRIPTION

Ibuprofen + Paracetamol (Alaxan[®] Tablet) is a round, two-layered, flat, beveled-edge tablet, debossed with “Alaxan” on the orange layer and plain on the white layer.

Ibuprofen + Paracetamol (Alaxan[®] FR Capsule) comes as a hard gelatin capsule. The cap is salmon pink opaque while the body is ivory opaque in color and printed with “Alaxan”.

WHAT IS IN THE MEDICINE?

The product contains a combination of Ibuprofen and Paracetamol. Ibuprofen belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (also known as NSAIDs). Like other NSAIDs, Ibuprofen works by changing the body’s chemical response to pain, swelling and fever resulting in relief of symptoms of inflammation (e.g., swelling, redness) and relief of pain and/or fever. Paracetamol is a fever reducer and pain reliever.

The combination of Ibuprofen and Paracetamol has a synergistic effect, i.e., they work together to improve overall effect. The anti-inflammatory activity of Ibuprofen + Paracetamol combination is greater compared with each individual ingredient. Pain relief is also improved with the combination.

STRENGTH OF THE MEDICINE

Each Ibuprofen + Paracetamol (Alaxan[®] Tablet and Alaxan[®] FR Capsule) contains 200 mg Ibuprofen and 325 mg Paracetamol.

WHAT IS THE MEDICINE USED FOR?

- Ibuprofen + Paracetamol (Alaxan[®] and Alaxan[®] FR) is used for the relief of mild to moderately severe pain of musculoskeletal origin such as muscle pain (myalgia), arthritis, rheumatism, sprain, strain, bursitis (inflammation of the fluid-filled sac or bursa that lies between a tendon and skin), tendonitis, backache, and stiff neck.
- Ibuprofen + Paracetamol (Alaxan[®] and Alaxan[®] FR) is also used for the relief of tension headache, dysmenorrhea, toothache, pain after tooth extraction and minor surgical operations.
- Ibuprofen + Paracetamol (Alaxan[®] and Alaxan[®] FR) is effective for fever reduction.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Like other NSAIDs, the lowest effective dose of Ibuprofen + Paracetamol should be used for the shortest possible time. This medicine is given orally (by mouth).

- **Adults and Children 12 years and older:** 1 tablet or capsule every 6 hours as needed or as directed by a doctor.
 - Do not take more than directed.
 - Do not take longer than 10 days, unless directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Do not take this medicine:

- If you are allergic to Paracetamol, Ibuprofen, Aspirin, and other NSAIDs. Ibuprofen, like other NSAIDs, may cause severe allergic reactions. Symptoms may include:
 - Hives (elevated, whitish or reddish patches on the skin with severe itching or prickling sensations)
 - Shock (anaphylactic) (a hypersensitivity reaction resulting in generalized skin lesions and itchiness, followed by low blood pressure and often accompanied by difficulty of breathing)
 - Facial swelling
 - Skin reddening
 - Asthma (wheezing)
 - Skin rash
 - Skin blisters
- If you have or have ever had kidney disease.
- If you develop signs and symptoms of liver abnormality (e.g., jaundice), stop taking this medicine and consult a doctor.
- Right before or after heart surgery
- If you have a history of stroke, heart attack, uncontrolled high blood pressure, or congestive heart failure
- If you have bronchospasm (constriction of air passages of the lung), angioedema (rapid swelling that occurs in the tissue just below the surface of the skin), nasal polyps or allergic-type reactions after taking Aspirin or other NSAIDs.
- If you are pregnant or breastfeeding unless advised by your doctor. It is especially important not to use an NSAID-containing product (e.g., Ibuprofen) during the last three 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.

UNDESIRABLE EFFECTS

Ibuprofen + Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of undesirable effects. No serious undesirable effects have been reported to date. Only minor allergic type reactions such as skin rashes which are expected with other NSAIDs (e.g., Aspirin, Naproxen, etc.) have been reported.

Ibuprofen shares the same undesirable effects as other NSAIDs.

Ibuprofen may cause stomach and intestinal undesirable effects such as ulceration and/or bleeding; other undesirable effects are indigestion, heartburn, nausea, vomiting, eating disorder (anorexia), diarrhea, constipation, mouth ulcers (stomatitis), flatulence, bloating, and abdominal pain.

Ibuprofen may also cause harmful effects to the kidney and the liver.

There have been occasional reports of undesirable effects involving the blood and blood-forming tissues.

There have also been occasional reports of dizziness, drowsiness, general ill feeling (malaise), lightheadedness, nervousness, headache, fatigue, mood swings (emotional lability), loss of sensation (paresthesia), hallucinations, and dream abnormalities.

Ibuprofen may cause undesirable effects involving the ears and eyes such as ringing in the ears (tinnitus), decreased hearing, loss of visual sharpness (amblyopia), inflammation or infection of the membrane lining the eyelids (conjunctivitis), inflammation of the optic nerve (optic neuritis), double vision (diplopia) and cataracts.

Skin rashes have been observed. There have been rare reports of Stevens-Johnson Syndrome, Lyell’s syndrome, and erythema multiforme which are serious types of allergy and may occur without warning. Symptoms of these serious types of allergy include multiple skin lesions, itching, fever, and joint pains.

Allergic reactions manifested as a syndrome of abdominal pain, fever chills, nausea and vomiting have occasionally occurred. Whole-body allergic reaction (anaphylaxis), constriction of air passages of the lung, dry mouth, gingival ulceration, and stuffy nose (rhinitis) have also been reported.

Other undesirable effects are fluid retention, increased blood pressure, low blood pressure, cerebrovascular accident (stroke) and palpitations.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

- Aspirin decreases the amount of Ibuprofen in the blood, while Phenylbutazone, Indomethacin, Salicylates, and other NSAIDs (e.g., Mefenamic Acid, Naproxen, Diclofenac, Indomethacin, Ketoprofen) increase the risk of stomach and intestinal bleeding in patients receiving Ibuprofen.
- When taken with blood thinning (anticoagulant) medicines (e.g., Warfarin, Dicumarol) or together with thrombolytic agents (e.g., Streptokinase), Ibuprofen may cause stomach and intestinal bleeding.
- Ibuprofen increases the amount of lithium in the blood, interfering with lithium elimination in the kidney.
- Ibuprofen may cause acute reduction in kidney function and blood pressure response to ACE inhibitors (e.g., Captopril, Enalapril)
- Ibuprofen may reduce the effect of diuretics such as Furosemide and Thiazide.
- Medicines which stimulate the enzymes responsible for the metabolic activation of Paracetamol such as medicines for convulsion (e.g., Phenobarbital) may increase susceptibility to the harmful effects to the liver.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you missed a dose, take the next dose if still needed for pain and/or fever or inflammation and the subsequent dose every 6 hours thereafter.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

Keep the product out of reach and sight of children.

Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Overdosage of Paracetamol usually involves 4 phases with the following signs and symptoms:

- I. Eating disorder, nausea, vomiting, malaise, and excessive sweating
- II. Right upper abdominal pain or tenderness, liver enlargement which may be characterized by abdominal discomfort of “feeling full”, elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time, and occasionally decreased urine output
- III. Eating disorder, nausea, vomiting, and malaise recur and signs of liver (e.g., jaundice) and possibly kidney failure
- IV. Recovery or progression to fatal complete liver failure

The most frequently reported symptoms of Ibuprofen overdose include abdominal pain, nausea, vomiting, fatigue (lethargy) and drowsiness. Other symptoms include headache, ringing in the ears (tinnitus), brain depression, and convulsions. Excessive acidity of the blood (metabolic acidosis), coma, acute kidney failure and absence of spontaneous breathing (apnea) may rarely occur.

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. Quick medical attention is important for adults as well as for children even if you do not notice any signs or symptoms.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

- This medicine should be given with care to patients with kidney or liver disease including patients taking other drugs that affect the liver.
- Do not use with any other product containing Paracetamol, Ibuprofen or other NSAIDs. If you are taking cough and cold preparations, other fever reducers or pain relievers, check if they contain Paracetamol (or Acetaminophen), Ibuprofen or other NSAIDs.
- Do not take more than the recommended dose or duration of treatment.
- This medicine may cause stomach bleeding. The chance is higher if you:
 - Are 60 years old or older
 - Have had stomach ulcers or bleeding problems
 - Take a blood thinning (anticoagulant) (e.g., Warfarin) or steroid (e.g., Prednisone) drug
 - Take other drugs containing an NSAID (e.g., Aspirin, Naproxen, or others)
 - Have 3 or more alcoholic drinks every day while using this product
 - Take more than the recommended dose or take more than the directed duration of treatment
- If stomach upset occurs, take this medicine with food or milk.
- Long term continuous use may increase the risk of heart attack or stroke.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Ask a doctor before use if you have :

- Problems or serious undesirable effects from taking pain relievers or fever reducers
- Stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- Ulcers
- Bleeding problems
- High blood pressure
- Heart or kidney disease
- Taken a medicine to help reduce the amount of water in the body (diuretic)
- Reached age 60 years or older

Ask a doctor before use if you are:

- Taking any other drug containing an NSAID such as Aspirin, Naproxen, Mefenamic Acid and others
- Taking a blood thinning (anticoagulant) or steroid (e.g. Prednisone) medicine
- Under a doctor’s care for any serious condition
- Taking any other drug

Stop use and ask a doctor if:

- You feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding.
- Pain gets worse or lasts more than 10 days
- Fever gets worse or lasts more than 3 days
- Stomach pain or upset gets worse or lasts
- Any new symptoms appear

If you are pregnant or breastfeeding, ask a doctor before use.

AVAILABILITY

Ibuprofen + Paracetamol (Alaxan[®] Tablet) available in Box of 10's and 500's (in Blister Foil x 10's)

Ibuprofen + Paracetamol (Alaxan[®] FR Capsule) available in Box of 10's and 100's (in Blister Foil x 10's)

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