IBUPROFEN + PARACETAMOL

MUSKELAX

200 mg/325 mg Tablet

Nonsteroidal Anti-inflammatory Drug/Analgesic/Antipyretic

FORMULATION

Each tablet contains:

- Ibuprofen ................................................. 200 mg
- Paracetamol .............................................. 325 mg

PRODUCT DESCRIPTION

Ibuprofen 200 mg + Paracetamol 325 mg (Muskelax) is a white, capsule-shaped tablet.

WHAT IS IN THE MEDICINE?

This 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 the 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 the ibuprofen + paracetamol combination is greater compared with each individual ingredient. Pain relief is also improved with the combination.

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, sprain, strain, bursitis (inflammation of the fluid-filled sac or bursa that lies between a tendon and skin), tendinitis, backache, and stiff neck.

- For the relief of tension headache, dysmenorrhea, toothache, pain after tooth extraction and minor surgical operations.

- 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 and may be taken with food or milk if stomach upset occurs.

**Adults and Children 12 years and older:** 1 tablet every 6 hours as needed, or, as directed by a doctor.

- Do not exceed 6 tablets in each 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?

- If you are allergic to paracetamol, ibuprofen, aspirin or other NSAIDs, or to any ingredient in the product

- If you are taking aspirin or other NSAIDs

- If you have bronchospasm (constriction of air passages of the lungs), 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 have had or are suffering from stomach ulcers, bleeding or other stomach problems
- 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 severe liver or kidney disease
- Avoid long-term use in patients with anemia
- During the last 3 months of pregnancy

UNDISIRABLE EFFECTS

IBUPROFEN

Undesirable effects from the use of ibuprofen are rare, but they may occur. Tell your doctor if you experience any undesirable effect.

*Stomach/Gut:* Abdominal pain, nausea, vomiting, heartburn, diarrhea, constipation, indigestion, decreased appetite, flatulence, bloating, stomach ulceration and/or bleeding, gastritis, vomiting with blood, passing black or bloody stools, mouth ulcers, worsening of colitis and Crohn’s disease, pancreatitis

*Cardiovascular:* Swelling of tissues usually in the lower limbs (edema), fluid retention, increased blood pressure, low blood pressure, irregular heartbeat, chest pain, cerebrovascular accident (stroke), heart failure

*Nervous System:* Dizziness, headache, nervousness, depression, sleeplessness, confusion, mental mood swings (emotional lability), drowsiness, anorexia, hallucinations, dream abnormalities, vertigo, loss of sensation; inflammation of the membranes that cover the brain and spinal cord (aseptic meningitis) has occurred rarely

*Skin:* Skin rashes, blisters, itching, hives, loss of hair, sensitivity to light or the sun; symptoms of serious allergies (e.g., Stevens-Johnson Syndrome, toxic epidermal necrolysis, and erythema multiforme)

*Blood:* Low white blood cell count (i.e., leucopenia, neutropenia, agranulocytosis, eosinophilia, pancytopenia), low platelet count, anemia, blood does not clot properly, decrease in hemoglobin and hematocrit, bleeding episodes

*Kidneys:* Blood in the urine, excess serum proteins in the urine, kidney damage and kidney failure
**Liver:** Abnormal liver function tests, liver disorders especially with long-term treatment, jaundice, inflammation of the liver (hepatitis), liver failure

**Metabolic:** Benign enlargement of the male breasts, low blood sugar, increased acid in blood and body tissues

**Special Senses:** Ringing in the ears, blurred and/or decreased visual sharpness (amblyopia), depressed vision in the visual field (scotoma) and/or changes in color vision, inflammation or infection of the membrane lining the eyelids (conjunctivitis), double vision, cataracts, inflammation of the optic nerve

**Allergic Reactions:** Syndrome of abdominal pain, fever, chills, nausea and vomiting; whole-body allergic reaction (anaphylaxis), autoimmune disorders (e.g., lupus erythematosus syndrome, Henoch–Schönlein purpura), rapid swelling beneath the skin (angioedema), serum sickness, dry mouth, gingival ulceration, stuffy nose, worsening of asthma, constriction of air passages of the lungs, wheezing or difficulty in breathing

**PARACETAMOL**

Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects.

Skin rashes, hypersensitivity reactions, changes in the number of white blood cells and platelets, and minor stomach and intestinal disturbances have been reported.

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

- Ibuprofen may interfere with the anti-platelet activity of aspirin, thus limiting aspirin’s cardioprotective effect

- Phenylbutazone, indomethacin, salicylates (e.g., aspirin), and other NSAIDs (e.g., mafenamic acid, naproxen, diclofenac, ketoprofen), including COX-2 inhibitors (e.g., celecoxib, etoricoxib), 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 (increased risk of lithium toxicity) by reducing lithium excretion.
- Ibuprofen may cause acute reduction in kidney function and blood pressure response to ACE inhibitors (e.g., captopril, enalapril, ramipril, imidapril, fosinopril, lisinopril) and angiotensin II receptor antagonists (e.g., losartan, telmisartan)

- Ibuprofen may reduce the effect of diuretics such as furosemide and thiazide.

- Ibuprofen reduces methotrexate excretion from the body, thus increasing the risk of methotrexate toxicity.

- Ibuprofen may increase plasma concentrations of cardiac glycosides (e.g., digitalis), worsen cardiac failure and reduce kidney function

- NSAIDs increase aminoglycoside toxicity by decreasing the excretion of aminoglycosides (e.g., amikacin, gentamicin, neomycin, tobramycin)

- Corticosteroids (e.g., prednisone, prednisolone) and selective serotonin reuptake inhibitors (SSRIs; e.g., citalopram, escitalopram, sertraline) may increase the risk of stomach bleeding with ibuprofen

- *Ginkgo biloba* may enhance the risk of bleeding when given with ibuprofen

- There is an increased risk of nephrotoxicity (kidney damage) when ciclosporin or tacrolimus are given together with ibuprofen

- Ibuprofen should not be used for 8-12 days after mifepristone administration because it can reduce the effect of mifepristone

- A possible increased risk of convulsions may occur when ibuprofen is taken with quinolones (e.g., ofloxacin, levofloxacin, norfloxacin, ciprofloxacin, sparfloxacin, moxifloxacin).

- An increased risk of blood problems such as bleeding into a joint (hemarthrosis) and bruising (hematoma) may result when ibuprofen is given with antiviral medicines such as zidovudine.

- The absorption of paracetamol may be accelerated by metoclopramide or domperidone and reduced by cholestyramine.

- 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.
• An increase in the International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding, may be observed when using paracetamol and warfarin at the same time. Paracetamol increases the anticoagulation effect of warfarin.

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 OVERDOSE

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), central nervous system depression, and convulsions. Excessive acidity of the blood (metabolic acidosis), coma, acute kidney failure and absence of spontaneous breathing (apnea) may rarely occur.

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
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

- **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 pricking 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)

- **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 or for a longer time than directed

- **Liver Warning:** This product contains paracetamol. Severe liver damage may occur if:

  - 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

- Do not use with any other medicine containing paracetamol or ibuprofen (prescription or nonprescription). If you are not sure whether a medicine contains paracetamol or ibuprofen ask a doctor.

- The risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Ask a doctor before use if you are:

- Having problems or serious side effects from taking pain relievers or fever reducers
- Taking ibuprofen, paracetamol, aspirin or other NSAIDs
- Taking other medicines
- Under a doctor’s care for any serious condition

Ask a doctor before use if:

- Stomach bleeding warning applies to you
- 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 a history of stomach problems, 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 liver or kidney problems
- You have asthma
- You suffer from systemic lupus erythematosus (SLE) or other autoimmune diseases
- You are taking warfarin, a blood thinning medicine

Stop use and ask a doctor if:

- 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
• An allergic reaction occurs
• New symptoms occur
• Symptoms do not get better
• Headache is persistent
• Redness or swelling is present in the painful area
• Pain gets worse or lasts more than 10 days
• Fever gets worse or lasts more than 3 days

If you are pregnant or breastfeeding, ask a doctor before use. It is especially important not to use 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.

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL)

Note to ULCH: PIL revision date should be the date when the PIL is approved by the Food and Drug Administration (FDA).