Ibuprofen

Medicol® Advance

200 mg SOFTGEL CAPSULE

Non-steroidal Anti-inflammatory Drug / Analgesic / Antipyretic

FORMULATION
Each softgel capsule contains:
Ibuprofen……200 mg

PRODUCT DESCRIPTION
Ibuprofen (Medicol® Advance) 200 mg is a red, transparent softgel capsule containing a clear, red solution.

WHAT IS IN THE MEDICINE?
This product contains ibuprofen which belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). Like other NSAIDs, ibuprofen works by changing the body's chemical response to pain, inflammation and fever resulting in relief of symptoms of inflammation (e.g., swelling, redness) and relief of pain and/or fever.

STRENGTH OF THE MEDICINE See Formulation.

WHAT IS THE MEDICINE USED FOR?
- For the relief of headache;
- For the relief of toothache, muscular aches, minor arthritis pain, backache, minor aches and pains associated with the common cold, and pain of menstrual cramps (dysmenorrhea);
- For fever reduction.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Like other NSAIDs, the lowest effective dose of ibuprofen should be used for the shortest possible time.
This medicine is given orally (by mouth).

Adults and Children 12 years and older: 1 softgel capsule with a glassful of water every 4 to 6 hours as needed, or, as directed by a doctor.
Children under 12 years old: Consult a doctor before use.
Do not take more than directed.
Do not exceed 6 softgel capsules in 24 hours, unless directed by a doctor.
Do not take longer than 10 days, unless directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If you have ever had an allergic reaction to ibuprofen, aspirin or other NSAIDs or to any ingredient in the medicine
- 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 are taking aspirin or other NSAIDs, lithium or methotrexate
- 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 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
- If you are pregnant or breastfeeding

UNDESIRABLE EFFECTS
Undesirable effects from the use of ibuprofen are rare, but they may occur. Tell your doctor if you experience any undesirable effect.
Central Nervous System: Dizziness, drowsiness, general ill feeling (malaise), lightheadedness, nervousness, headache, fatigue, mood swings (emotional lability), loss of sensation (paresthesia), hallucinations, and dream abnormalities.
Gastrointestinal: Stomach ulceration and/or bleeding, indigestion, heartburn, nausea, vomiting, eating disorder (anorexia), diarrhea, constipation, mouth ulcers (stomatitis), flatulence, bloating, and abdominal pain.
Kidneys: blood in the urine, kidney damage and kidney failure
Liver: Abnormal liver function tests, jaundice, inflammation of the liver and liver failure
Blood: Blood does not clot properly, anemia and low white blood cell count
Cardiovascular: Fluid retention, increased blood pressure, low blood pressure, cerebrovascular accident (stroke), and palpitations.
Special senses: 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: Skin rashes; symptoms of serious allergies (e.g., Stevens-Johnson Syndrome, Lyell's syndrome, and erythema multiforme) which include multiple skin lesions, itch, fever, and joint pains.
Allergic reactions manifested as a syndrome of abdominal pain, fever, chills, nausea and vomiting. Whole-body allergic reaction (anaphylaxis), constriction of air passages of the lungs, dry mouth, gingival ulceration, and stuffy nose (rhinitis) have also been reported.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
- Blood concentrations of ibuprofen may be decreased when given together with aspirin
- Phenylbutazone, indomethacin, salicylates, and other NSAIDs (e.g., mefenamic acid, naproxen, diclofenac, 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.
- Corticosteroids (e.g., prednisone, prednisolone), selective serotonin reuptake inhibitors (SSRIs) [e.g., citalopram, escitalopram, sertraline] may increase the risk of stomach bleeding with ibuprofen
- Ibuprofen may cause acute reduction in kidney function and blood pressure response to ACE inhibitors (e.g., captopril, enalapril, ramipril, imidapril, fosinopril, lisinopril).
- Ibuprofen should not be used 8-12 days after mifepristone use because it can reduce the effect of mifepristone
- Ibuprofen may reduce the effect of diuretics such as furosemide and thiazide.
- Ibuprofen reduces methotrexate excretion from the body, thus increasing the risk of toxicity.
- Ibuprofen increases the amount of lithium in the blood (increased risk of toxicity) probably by reducing excretion of lithium.
- Ibuprofen may increase the plasma concentration of cardiac glycosides (e.g., digitalis), worsen cardiac failure and reduce renal function
- Ibuprofen may enhance the effect of phenytoin, an antiepileptic medicine
- There is an increased risk of nephrotoxicity (kidney damage) when ciclosporin or tacrolimus are given together with ibuprofen
- *Ginkgo biloba* may enhance the risk of bleeding when given with ibuprofen

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, take the next dose if still needed for pain and/or fever or inflammation and the subsequent dose every 4 to 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 25°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE
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.

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.

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)
  - Skin rash
  - Skin blisters
- If an allergic reaction occurs, stop use and seek medical help right away.
- **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
- If stomach upset occurs, take this medicine with food or milk.
- When using this product 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 other medicines
- Under a doctor's care for any serious condition
- 60 years old or older

Ask a doctor before use if:
- Stomach bleeding warning applies to you
- You have a history of stomach problems such as heartburn, upset stomach or stomach pain
- You have liver or kidney 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)
- Suffer from asthma
- Suffer from systemic lupus erythematosus (SLE) or other auto-immune diseases

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
- Pain gets worse or lasts more than 10 days
- Fever gets worse or lasts more than 3 days
- Redness and swelling is present in the painful area
- Any new symptoms appear

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.

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY: Alu/PVC Blister Pack x 5's and 10's (Box of 5's and 100's)
DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): OCTOBER 2018
DATE OF FIRST AUTHORIZATION: 11 JUNE 2008

Manufactured by BELMONT SOFTGEL PHARMA CORPORATION
Floridablanca Interchange, SCTEX, San Jose, Floridablanca, Pampanga
for **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

Reg. IPOPHIL P300000027767 DR-XY34641

Trusted Quality Healthcare