PROFEN®
IBUPROFEN PREPARATIONS

COMPOSITION:

1. **Profen® 200mg tablets**: Each film coated tablet contains Ibuprofen BP 200mg.
2. **Profen® 400mg tablets**: Each film coated tablet contains Ibuprofen BP 400mg.
3. **Profen® Suspension**: Each 5ml contains Ibuprofen BP 100mg.

INDICATIONS:

Profen® is indicated for the relief of fever and pain.

It is also used in the management of mild to moderate pain in conditions such as dysmenorrhoea, migraine and postoperative pain. **Profen** is also used in the management of pain and inflammation in such conditions as ankylosing spondylitis, osteoarthritis, rheumatoid arthritis and in other musculoskeletal and joint disorders such as sprains and strains.

DOSAGE AND ADMINISTRATION:

Profen® is taken orally preferably after meals or with milk.

ADULTS:

1. Analgesic dosage for adults usually is 1.2 to 1.8g daily in 3-4 divided doses. If necessary this may be increased to 2.4g. A lower maintenance dose of 0.6g-1.2g may be adequate in some patients.
2. For rheumatoid arthritis and osteoarthritis a dosage of 300 or 400mg every 3 or 4 hours and which may be adjusted according to the patients need will be necessary, the maximum total daily dosage being 3.2g.

CHILDREN:

1. Analgesic dosage is 20mg per kg body weight daily in divided doses, the maximum dose being 500mg for children under 30Kg body weight.
2. For Juvenile Rheumatoid Arthritis upto 40mg per Kg of body weight daily in divided doses may be given.

SIDE EFFECTS:

Side effects occurring with an incidence greater than 1% may be grouped as follows:-

1. **Gastrointestinal**: epigastric pain, heartburn, diarrhoea, abdominal distress, nausea and vomiting, indigestion, constipation and abdominal cramps or pain.
2. **CNS**: vertigo, headache, anorexia and nervousness.
3. **Hypersensitivity**: rash, pruritus and oedema.
4. **Special senses:** hearing disturbances such as tinnitus.
5. **Cardiovascular:** fluid retention.

Side effects occurring with an incidence less than 1% may be grouped as follows:-

1. **Gastrointestinal:** Gastric or duodenal ulcers with bleeding and or perforation.
2. **CNS**: depression, insomnia and drowsiness.
3. **Hypersensitivity:** Vesiculobullous eruptions, urticaria, erythema multiforme, fever, hepatotoxicity, cystitis, haematuria, bronchospasms in some asthmatics and aseptic meningitis mostly in those with connective tissue disorders such as systemic lupus erythrematosus.
4. **Special senses**: blurred vision, scotomata and other changes in visual colour perception and toxic amblyopia.
5. **Blood disorders**: anaemia, thrombocytopenia, eosinophilia and agranulocytosis.
6. **Cardiovascular**: Congestive heart failure in patients with marginal cardiac function and elevated blood pressure particularly in the elderly, reversible acute renal failure particularly in patients with pre-existing renal impairment.

PRECAUTIONS, CAUTIONS AND CONTRAINDICATIONS:

Profen® should be given under close supervision to patients with gastric ulceration or with history of upper gastrointestinal tract disease. Caution should also be exercised when it is administered to the elderly, those on anticoagulant therapy and in cases of renal, cardiac or hepatic impairment.

Profen® is not recommended during pregnancy and in nursing mothers. Its use is contraindicated in persons known to be hypersensitive to it and in persons with the syndrome of nasal polyps, angioedema and bronchospastic reactivity to aspirin or other NSAIDs.

In case of visual disturbance, treatment with Profen should be discontinued and an ophthalmological examination undertaken.

PHARMACOLOGY:

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) that has analgesic as well as antipyretic activities. It exerts its action through the inhibition of cyclo-oxygenase enzyme. 200mg of Ibuprofen has the analgesic activity comparable to 650mg of aspirin. The beneficial effects of Ibuprofen can be demonstrated by its ability to reduce joint swelling, pain and duration of morning stiffness. It also improves functional capacity as is indicated by an increase in grip strength, delay in time to onset of fatigue and decrease in time to walk a given distance.

PHARMACOKINETICS:

Ibuprofen is rapidly absorbed from the gastrointestinal tract, the peak plasma concentration being attained in 1 to 2 hours after ingestion. The absorbed drug is extensively bound to plasma proteins and has a half life of 1.8 to 2.0 hours.

It is rapidly metabolised and also rapidly excreted mostly through urine. Only about 1% is excreted unchanged while about 14% is excreted as the conjugated ibuprofen in urine. The remaining drug is excreted mostly as various metabolites and their conjugates the excretion being virtually complete 24 hours after the last dose.

LEGAL CATEGORY: Prescription Only Medicine (POM).

THERAPEUTIC CATEGORY: ATC: M01A (Non-steroidal antiinflammatory & antirheumatic) and NO2B (analgesic—antipyretic)

STORAGE CONDITIONS:Profen® should be kept in a dry place below 30°C and protected from light. They should be kept out of reach of children.

SHELF LIFE: As per the product label.

PRESENTATION:

Profen®-200 tablets: Available in Blister Packs of 100's and bulk packs of1000's.

Profen®-400 tablets: Available in Blister Packs of 100's and bulk packs of 500's.

Profen®Suspension: Available in 60 and 100ml amber coloured bottles.

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LICENCE HOLDER: LABORATORY & ALLIED LTD.

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