1.4 PRODUCT INFORMATION.
1.4.1 Prescribing information (Summary of Product Characteristics)
1. Name of the medicinal product.
Profen Suspension.
2. Qualitative and quantitative composition.
Each 5mL contains: Ibuprofen BP 100mg.

3. Pharmaceutical form.
Suspension for oral administration.
Orange, sweet suspension. Packed in 60mL/100mL amber glass/PET bottle and contained in a unit box with literature insert.

4. Clinical particulars.
4.1 Therapeutic 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 dysmenorrhea, migraine and postoperative pain.
It 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.

4.2 Dosage and Administration.
Profen is taken orally preferably after meals or with milk.
Adults
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 0.6 – 1.2g may be adequate in some patients.
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
Analgesic dosage is 20mg per kg body weight daily in divided doses, the maximum dose being 500mg for children under 30kg body weight.
For Juvenile Rheumatoid Arthritis up to 40mg per kg of body weight daily in divide doses may be given.

4.3 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 therapies 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.

4.4 Special warnings and precautions for use.
Profen should be given under close supervision to patients with gastric ulceration or with gastric ulceration or with history of upper gastrointestinal tract disease.
Caution should also be exercised when it is administered to the elderly 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.

4.5 Interaction with other medicinal products and other forms of interaction.
Ibuprofen should not be used in combination with:
Acetylsalicylic acid
Concomitant administration of ibuprofen and aspirin (acetylsalicylic acid) is not generally recommended (unless low-dose aspirin (not above 75mg daily) has been advised by a doctor), as this combination may increase the risk of adverse reactions.
Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose aspirin (acetylsalicylic acid) on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these

data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose aspirin (acetylsalicylic acid) cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use.
Other NSAIDs including cyclooxygenase-2 selective inhibitors: as these may increase the risk of adverse effects.
Ibuprofen should be used with caution in combination with:
Corticosteroids: may increase the risk of adverse reactions, especially of the gastrointestinal tract.
Antihypertensives and diuretics: NSAIDs may diminish the effects of these drugs. Diuretics can increase the risk of nephrotoxicity of NSAIDs.
Anticoagulants: NSAIDS may enhance the effects of anticoagulants, such as warfarin
Anti-platelet agents and selective serotonin-reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding.
Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.
Lithium: There is evidence for potential increase in plasma levels of lithium.
Methotrexate: There is the potential for increased plasma levels of methotrexate.
Ciclosporin: Increased risk of nephrotoxicity.
Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
Tacrolimus: Possible increase risk of nephrotoxicity when NSAIDs are given with tacrolimus.
Zidovudine: There is evidence of an increased risk of haemarthroses and haematoma in HIV positive haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.
Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

4.6 Pregnancy and lactation.
Pregnancy:
While no teratogenic effects have been demonstrated in animal experiments, use of ibuprofen should, if possible, be avoided during the first 6 months of pregnancy.
During the 3rd trimester, ibuprofen is contraindicated, as there is a risk of premature closure of the foetal ductus arteriosus with possible persistent pulmonary hypertension. The onset of labour may be delayed and duration of labour increased, with increased bleeding tendency in both mother and child.
Lactation:
In limited studies ibuprofen appears in the breast milk in very low concentrations and is unlikely to affect the breast-fed infant adversely.

4.7 Effects on ability to drive and use machines.
None known

4.8 Undesirable 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 occuring with an incidence less than1% 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 erythematosus.
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.

4.9 Overdose
In children ingestion of more than 400mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5-3 hours.
Symptoms
Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious

poisoning, toxicity is seen in the central nervous system, manifesting as vertigo, headache, respiratory depression, dyspnoea, drowsiness, occasionally excitation and disorientation or coma. Occasionally patents develop convulsions. In serious poisoning, hypotension, hyperkalaemia, and metabolic acidosis may occur and the prothrombin time / INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

Management

Should be symptomatic and supportive and include maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patients present within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5. Pharmacological properties.

5.1 Pharmacodynamic properties.

Pharmacotherapeutic group: Anti-inflammatory and Antirheumatic Products, Non-Steroids, Propionic acid derivatives.
ATC Code: M01AE01.
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.

5.2 Pharmacokinetic properties.

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 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.

5.3 Preclinical safety data.

No relevant information additional to that already contained elsewhere in the SmPC.

6. Pharmaceutical particulars.

6.1 List of excipients.

- Xanthan Gum 200 Mesh BP.
- Sorbitol 70% Solution BP.
- Glycerine BP.
- Sodium Methyl Paraben BP.
- Sodium Propyl Paraben BP.
- Sodium Sacharrin BP.
- Polysorbate 80 BP.
- Citric Acid BP.
- Disodium EDTA BP.
- Sunset Yellow Soluble Colour IH.
- Raspberry Essence Liquid IH.
- Vanilla Essence Liquid IH.
- Purified Water BP.

6.2 Incompatibilities.

None known.

6.3 Shelf life.

3 years.

6.4 Special precautions for storage.

Store in a dry place, below 30°C.
Protect from light.
Do not freeze.
Keep all medicines out of reach of children.
Replace cap securely after use.

6.5 Nature and contents of container.

Orange, sweet suspension. Packed in 60mL/100mL amber PET/glass bottle and contained in a unit box with literature insert.

6.6 Special precautions for disposal and other handling.
Any unused medicinal product or waste material should be disposed off in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses Marketing Authorization Holder:
Company name: LABORATORY & ALLIED LTD.
Address: PLOT NO: 209/10349 OFF MOMBASA ROAD,
P.O BOX 42875, CODE 00100 NAIROBI, Country: KENYA
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Telephone: + 254 – 20-8040306
Telefax: +254 – 020 - 8040309
E-Mail: info@laballied.com.

8. Marketing authorisation number(s).
Kenya: H91104.

9. Date of first authorisation/renewal of the authorisation.
Authorisation: 12/04/1991.
Renewal: Retained annually.

10. Date of revision of the text
May 2023.