# Daprofen® Suspension

**Ibuprofen 100mg/5ML**

**Qualitative and quantitative composition:**

Each 5ml contains :Ibuprofen BP 100 mg

**Excipients:**

Sugar, Sodium methyl paraben, Sodium propyl paraben, Sodium Benzoate, Sodium CMC, Xanthan Gum, Veegum, Tween 80, Sodium Saccharin, Glycerin, Sunset yellow, Sodium citrate, Bronopol, Orange flavour and Purified water

**Pharmaceutical form:**

Orange viscous suspension free from visible evidence of contamination with an orange flavour, packed in 60ml amber coloured PET bottles.

**Pharmacology**

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids; propionic acid derivatives. ATC code: M01AE01

Ibuprofen has shown anti-inflammatory, antipyretic, and analgesic activity in humans. The exact mechanisms of action of the drug have not been clearly established, but many of the actions appear to be associated principally with the inhibition of prostaglandin synthesis. Ibuprofen inhibits synthesis of prostaglandins in body tissues by inhibiting cyclooxygenase; at least 2 isoenzymes, cyclooxygenase-1 (COX-1) and -2 (COX-2) (also referred to as prostaglandin G/H synthase-1 [PGHS-1] and -2 [PGHS-2], respectively), have been identified that catalyze the formation of prostaglandins in the arachidonic acid pathway. Ibuprofen, like other prototypical NSAIAs, inhibits both COX-1 and COX-2. Although the exact mechanisms have not been clearly established, NSAIAs appear to exert anti-inflammatory, analgesic, and antipyretic activity principally through inhibition of the COX-2 isoenzyme; COX-1 inhibition presumably is responsible for the drugs' unwanted effects on GI mucosa and platelet aggregation. Higher doses usually are required for anti-inflammatory effects than for analgesia.Ibuprofen inhibits platelet aggregation and prolongs bleeding time but does not affect prothrombin time or whole blood clotting time.

**Pharmacokinetics:**

Ibuprofen is rapidly absorbed from the gastrointestinal tract, peak serum concentrations occurring 1-2 hours after administration. The elimination half-life is approximately 2 hours. Ibuprofen is metabolised in the liver to two inactive metabolites and these, together with unchanged ibuprofen, are excreted by the kidney either as such or as conjugates. Excretion by the kidney is both rapid and complete. Ibuprofen is extensively bound to plasma proteins.

**Therapeutic indications:**

Ibuprofen Suspension is indicated for its analgesic and anti-inflammatory effects in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis ,other non-rheumatoid (seronegative) arthropathies ,non-articular rheumatic conditions, peri-articular conditions such as frozen shoulder (capsulitis), bursitis, tendinitis, tenosynovitis and low back pain; also used in soft-tissue injuries such as sprains and strains.

Ibuprofen Suspension is also indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhoea, dental and post-operative pain and for symptomatic relief of headache including migraine headache and in short-term use for the treatment of pyrexia in children

**Posology and method of administration:**

Route of administration: Oral administration.

Adults and children over 12 years of age : The recommended dosage of Ibuprofen is 1200-1800 mg daily in divided doses. Some patients can be maintained on 600-1200 mg daily. Total daily dose should not exceed 2400 mg.

Children: The daily dosage of Ibuprofen is 20 mg/kg of bodyweight in divided doses. This can be achieved as follows:

1-2 years: One 2.5 ml spoonful (50 mg) three to four times a day.

3-7 years: One 5 ml spoonful (100 mg) three to four times a day.

8-12 years: Two 5 ml spoonfuls (200 mg) three to four times a day.

Not recommended for children weighing less than 7 kg.

In juvenile rheumatoid arthritis, up to 40 mg/kg of bodyweight daily in divided doses may be taken.

**Contraindications:**

Ibuprofen is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. Should not be used in patients who have previously shown hypersensitivity reactions (e.g. asthma, urticaria, angioedema or rhinitis) after taking ibuprofen, aspirin or other NSAIDs.

Contraindicated in patients with a history of gastrointestinal bleeding or perforation, related to previous NSAID therapy. Also should not be used in patients with active, or history of, recurrent peptic ulcer or gastrointestinal haemorrhage (two or more distinct episodes of proven ulceration or bleeding). and to patients with conditions involving an increased tendency to bleeding.

Contraindicated in patients with severe heart failure (NYHA Class IV), hepatic failure and renal failure and during the last trimester of pregnancy

**Special warnings and precautions for use:**

The risk of potentially serious adverse GI effects should be considered in patients receiving ibuprofen, Since peptic ulceration and/or GI bleeding have been reported in patients receiving the drug, patients should be advised to promptly report signs or symptoms of GI ulceration or bleeding to their clinician.

Geriatric individuals appear to tolerate GI ulceration and bleeding less well than other individuals

Caution is required to patients suffering from, or with a previous history of, bronchial asthma, chronic rhinitis or allergic diseases since , Renal and hepatic impairment, Cardiovascular and cerebrovascular effects.Haematological effects, Hypersensitivity to NSAIDs and ulcerative colitis or Crohn's disease

**Interaction with other medicinal products**

Ibuprofen should be avoided in combination with:

Anti-coagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin

Anti-platelet agents: Increased risk of gastrointestinal bleeding

Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine.

Sulfonylureas: NSAIDs may potentiate the effects of sulfonylurea medications.

Methotrexate: NSAIDs may inhibit the tubular secretion of methotrexate and reduce clearance of methotrexate.

Cardiac glycosides: NSAIDs may exacerbate heart failure, reduce glomerular filtration and increase plasma cardiac glycoside (e.g. digoxin) levels.

Antihypertensives, beta-blockers and diuretics: NSAIDs may reduce the effect of antihypertensives, such as ACE inhibitors, beta-blockers and diuretics.

Lithium: There is evidence for potential increases in plasma levels of lithium.

Ciclosporin: Increased risk of nephrotoxicity

Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus

Cholestyramine; The concomitant administration of ibuprofen and cholestyramine may reduce the absorption of ibuprofen in the gastrointestinal tract.

**Pregnancy and lactation:**

Ibuprofen inhibits prostaglandin synthesis and release, which may cause dystocia, interfere with labor, and delay parturition. Inhibitors of prostaglandin synthesis may have adverse effects on the fetal cardiovascular system (e.g., premature closure of the ductus arteriosus). Use of ibuprofen is not recommended during pregnancy (especially during the last trimester) or during labor and delivery.

Although ibuprofen has not been reported to distribute into milk in lactating women, the manufacturers state that use of the drug in nursing women is not recommended because of the potential risk of inhibitors of prostaglandin synthesis in neonates.

**Effects on ability to drive and use machines:**

No effect on ability to drive and use machines.

**Undesirable effects:**

Ibuprofen can cause gastric mucosal damage, which may result in ulceration and/or bleeding.

Hypersensitivity reactions manifested as a syndrome of abdominal pain, fever, chills, nausea, and vomiting have occasionally occurred during ibuprofen therapy. Anaphylaxis, anaphylactoid reactions, and bronchospasm have also occurred.

Although a causal relationship has not been established, serum sickness, lupus erythematosus syndrome, Henoch-Schönlein vasculitis, and angioedema have also been reported during therapy with the drug. Other adverse effects of ibuprofen include dry mouth, gingival ulceration, and rhinitis.

Although a causal relationship has not been established, gynecomastia, hypoglycemic reactions, and acidosis have also been reported during therapy with the drug.

**Overdose:**

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 drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning, 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

Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents 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.

**Shelf life:** 36 months from the date of manufacture.

**Special precautions for storage:**

Keep all medicines out of reach of children

Store in a dry place, below 30°C, protected from light.

**Nature and contents of container:**

Suspension packed in 60ml/100ml amber coloured pet bottles then in unit box.

**Marketing authorization holder:**

DAWA Limited,

Plot No. 7879/8, Baba Dogo Road, Ruaraka.

P. O. Box 16633 – 00620, Nairobi, Kenya

**Marketing authorization number(s):**

Kenya, License No.H2009/19998/673

**Legal category:** Prescription only medicine, (POM)

Manufactured by:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
P. O. Box 16633 – 00620, Nairobi, Kenya.

**Date of revision of the text:** **April 2017**