Ibupar® Tablets
Ibuprofen and Paracetamol

Qualitative and quantitative composition:
Each tablets contains: Ibuprofen BP 400mg and Paracetamol BP 325mg

Excipients:
Microcrystalline cellulose pH102,Polyvinylpyrrolidone, Maize Starch, Purified water, Purified talc, Magnesium Stearate, Colloidal anhydrous silica and Croscarmellose Sodium

Pharmaceutical form:
White coloured caplets, scored on one side and plain on the other side.

Pharmacology
ATC Code: M01AE51–anti-inflammatory and Antirheumatic products, non-steroids, Paracetamol is believed to exert its antipyretic effect by direct action on the hypothalamic heat-regulating center to block the effects of endogenous pyrogens. This results in increased heat dissipation through sweating and vasodilation.
Its analgesic effect may be related to an elevation of the pain threshold probably by inhibition of prostaglandin synthesis in the CNS.
Ibuprofen has shown anti-inflammatory, antipyretic, and analgesic activity and it exerts its anti-inflammatory, analgesic, and antipyretic activity principally through inhibition of the COX-2 isoenzyme, which is involved in the generation of pain and inflammatory responses in the body.

Pharmacokinetics:
Paracetamol is completely and rapidly absorbed via gastrointestinal tract after oral administration with a peak serum levels occurring in 15 – 45 minutes with a bioavailability of 96% ± 10%. It is 25% protein-bound.
Plasma concentrations do not correlate well with analgesic effect, but do correlate with toxicity.
Approximately 90% to 95% is metabolized by hepatic microsomal enzymes. It is excreted in the urine. The average elimination half-life ranges from 1 to 4.
Ibuprofen is well absorbed orally; approximately 80% of an oral dose is absorbed from the GI tract. Absorption rate is slower and plasma concentrations are reduced when ibuprofen tablets or suspension are taken with food; however, the extent of absorption is not affected. The antipyretic and anti-inflammatory effects of ibuprofen suspension begin within 1 hour after oral administration and peaks within 2-4 hours. Approximately 90–99% of a dose is bound to plasma proteins. The plasma half-life of the drug has been reported to be 2–4 hours.

Therapeutic indications:
Ibupar tablets is indicated for the relief of pain and inflammatory conditions associated with sprains, sports injuries, abscesses, dysmenorrhoea, sinusitis, fibrosis, dental processes and other miscellaneous conditions causing mild to moderate pain.
It is also used in conditions causing an increase in body temperature.

Posology and method of administration:
Route of administration: Oral administration.
Dosage
Adults and children above 12yrs:
1 – 2 tablets every 6 hours preferably after meals.
Do not take more than 8 tablets in 24 hours and do not take tablets more frequently than every 4 hours.
Maximum daily dose of Paracetamol : 4000mg.
Do not exceed the stated dose.
Should symptoms persist, consult your doctor.

Contraindications:
Ibupar is contraindicated in patients with known hypersensitivity to ibuprofen, Paracetamol or any other excipients. Administer the preparation cautiously to patients with anemia, hepatic or renal disease, to patients with a history of gastrointestinal disease, increased risk of gastrointestinal bleeding, decreased renal function, in symptomatic cardiac arrhythmias or palpitations, after acute myocardial infarction and a history of peptic ulcer disease. During the last trimester of pregnancy due to risk of premature closure of the foetal ductus arteriosus with possible pulmonary hypertension

Special warnings and precautions for use:
Should be given with care to patients with impaired kidney or liver function or patients with alcohol dependence an also contraindicated in patients with a history of hypersensitivity reactions for the one of these products. The risk of potentially serious adverse GI effects should be considered in patients receiving ibuprofen, particularly in patients receiving chronic therapy with the drug. 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.

Interaction with other medicinal products
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of Paracetamol with increased risk of bleeding; occasional doses have no significant effect.
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.
Ibuprofen can antagonize the irreversible platelet-aggregation inhibition of aspirin and therefore may limit the cardio protective effects of aspirin in patients with increased cardiovascular risk.
Ibuprofen has been reported to increase plasma or serum lithium concentrations by 12–67% and to reduce renal lithium clearance. NSAIDs may reduce the natriuretic effect of furosemide or thiazide diuretics.
Zidovudine: Increased risk of haematological toxicity with NSAIDS are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

Pregnancy and lactation:
Paracetamol crosses the placental barrier and is excreted in breast milk. Ibuprofen appears in the breast milk in very small concentrations and is likely to affect the breast-feed infant adversely. Whilst, human and animal studies have not identified any risk to pregnancy or embryofetal development, the use of Ibupar during pregnancy should be avoided if possible,. Human studies have not identified any risk to lactation or the breast-fed offsprings

Effects on ability to drive and use machines:
No effect on ability to drive and use machines.
Undesirable effects:
The most common adverse reactions include:
• Nausea, vomiting, diarrhea, abdominal cramps, abdominal pain, loss of appetite.
• Rash, urticaria, itching, unusual bruising, erythema
•Hypotension, muscular weakness, drowsiness, tinnitus, and euphoria and occasionally headache.
•Tachycardia, anxiety, restlessness, insomnia, skin rashes and urinary retention.
Overdose:
Paracetamol overdose may cause liver failure. Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present. Administration of N-acetylcysteine or methionine may be required.
Ibuprofen may cause nausea, vomiting and tinnitus, but more serious toxicity is very uncommon. Gastric emptying is indicated if more than 100mg/kg has been ingested within the preceding 4 hours, followed by symptomatic measures and if necessary, correction of serum electrolytes. There is no specific antidote to ibuprofen.

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:
Blister pack of 1x10's in unit boxes.

Marketing authorization holder:
Dawa Limited,
Plot No. 7879/8, Baba Dogo Road, Ruaraka.
P. O. Box 16633 – 00620, Nairobi, Kenya

Legal category: Pharmacy Only

Manufactured by:

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

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