For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Rx Information

COMBIFLAM ®
Ibuprofen and Paracetamol Tablets
Anti-inflammatory Analgesic

Composition: Each uncoated tablet of Combiflam® contains Ibuprofen IP 400mg and Paracetamol IP 325mg

Therapeutic Indication: Management of mild to moderate pain and inflammation in conditions such as dysmenorrhoea, headache, including migraine, post-operative pain, dental pain, musculoskeletal and joint disorders, peri-articular disorders and soft tissue disorders (sprains and strains). It also reduces fever.

Dosage & Administration : Adults: 1 tablet 3 times a day.

Safety related information

Contraindications : Peteinets with hypersensitivity to ibuprofen, paracetamol or excipients, with history of hypersensitivity reactions with acetrylsalicylic acid or other NSAIDs, history of GI ulceration/perforation or bleeding; with defects in coagulation; severe hepatocellular insufficiency, renal or cardiac failure. Concomitant use with other NSAIDs (COX2specific inhibitors, acetylsalicylic acid above 75mg daily); with other Paracetamol products and during last trimester of pregnancy.

Pregnancy & Lactation: Administration of Combiflam® is not recommended during pregnancy & lactation.

Warnings & Precautions : Hepatoxicity may develop. Steven Johnson syndrome (SJS) and Toxic epidermal necrolysis (TEN) may occur. Discontinue treatment in case of any allergic skin reactions. Caution in patients with sensitivity to aspirin/ NSAIDs. Patients with known analgesic intolerance or known bronchial asthma must use after consulting physician. Caution in patients with allergic disease, associated with severe bronchospasm. Caution in patients with renal, cardiac, hepatic insufficiency, Glucose-6-phosphate- ehydrogenase deficiency, Gilbert´s syndrome, Chronic alcohol use including recent cessation of alcohol intake and Low glutathione reserves. Careful assessment in case of cardiovascular and Cerebrovascular diseases. Caution in pateints with history of hypertension, mild to moderate congestive heart failure; GI bleeding, ulceration or perforation have been reported with use of NSAIDs, any unusual abdominal symptoms should be reported by patients with a history of GI toxicity. Caution in patinets with SLE and mixed connective tissue disease for risk of aseptic meningitis. Side effects more frequent in elderly patients. Not recommended in women attempting to conceive.

Adverse Reactions: *Paracetamol:* thrombocytopenia, neutropenia, leucopenia, erythema, urticarial and rash.
Ibuprofen: Most commonly observed undesirable effects are gastrointestinal in nature (Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration.). Non-specific allergic reaction and anaphylaxis; respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema. Oedema, hypertension and cardiac failure during Cardiac, vascular disorders. Other adverse events include-rhinitis and meningitis aseptic; leukopenia, thrombocytopenia, neutropenia, agranulocytosis, aplastic anemia and haemolytic anemia. insomnia, anxiety, depression, confusional state, hallucinations; headaches, paraesthesia, dizziness, somnolence, nervousness; visual impairment, optic neuritis, toxic optic neuropathy; hearing impaired, vertigo, tinnitus; abnormal hepatic function, hepatic failure, hepatitis, jaundice; photosensitivity reaction, Rash, pruritus; impaired renal function, toxic nephropathy, nephrotic syndrome and renal failure; malaise, fatigue.

For full prescribing information please contact : **Sanofi India Ltd.,** Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai - 400072
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