Abridged Prescribing Information

COMBIFLAM ® (Ibuprofen and Paracetamol Tablets I.P.)
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.
Adults and adolescents weighing from 40 kg body weight (aged 12 years and above): Initial dose, 1 tablet of Combiflam®. If necessary, additional doses can be taken. The respective dosing interval should be chosen in line with the observed symptoms and the maximum recommended daily dose. It should not be below 6 hours. A total dose of 3 tablets of Combiflam® should not be exceeded in any 24-hour period. For short-term use only.
In adults and adolescents (12 to 18 years) Combiflam® tablet should not be used for more than 3 days in the case of fever or for more than 4 days for the treatment of pain unless it is recommended by a physician. If the symptoms persist or worsen the patient is advised to consult a physician. It is recommended that patients with sensitive stomachs take Combiflam® tablet with food. If taken shortly after eating, the onset of actions of Combiflam® tablet may be delayed. If this happens, do not take more Combiflam® tablet than recommended or until the correct re-dosing interval has passed.

Safety related information

Contraindications : Patients with hypersensitivity to ibuprofen, paracetamol or excipients, with history of hypersensitivity reactions with acetylsalicylic acid or other NSAIDs, history of, or an existing GI ulceration/perforation or bleeding; with defects in coagulation; severe hepatocellular insufficiency, renal or cardiac failure, active, or history of recurrent or existing peptic ulcer/haemorrhages (two or more distinct episodes of proven ulceration or bleeding), cerebrovascular or other active bleeding, adolescents under 40 kg body weight and children below 12 years of age, patients with severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake) and third 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. Caution in patients with allergic disease associated with severe bronchospasm. Caution in patients with renal, cardiac, hepatic insufficiency and sepsis, glucose-6-phosphate-dehydrogenase deficiency, Gilbert´s syndrome, chronic alcohol use including recent cessation of alcohol intake malnutrition and other sources of low glutathione reserves. Caution in patients with SLE and mixed connective tissue disease for risk of aseptic meningitis or hepatitis, congenital disorder of porphyrin metabolism (e.g. acute intermittent porphyria), gastrointestinal disorders (such as peptic ulcer, hiatus hernia or gastrointestinal bleeding) and chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease). In patients who suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders due to increased risk of allergic reactions occurring which may present as asthma attacks, Quincke's edema or urticaria. Concomitant use with other NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. Careful assessment in case of cardiovascular diseases such as uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/ or cerebrovascular disease. 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. Patients with platelet disorders should be monitored carefully. Side effects more frequent in elderly patients. Not recommended in women attempting to conceive. Use of Combiflam® Tablets should be avoided in case of varicella. Hypersensitivity to Combiflam® may progress to Kounis syndrome that may result in myocardial infarction. Symptoms include chest pain and allergic reaction. Oligohydramnios/Neonatal Renal Impairment may occur due to use of NSAIDs including Combiflam® at about 13 weeks gestation or later in pregnancy. Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported in association with Combiflam® treatment. Cases of Fixed Drug Eruption (FDE) and Generalised Bullous Fixed Drug Eruption (GBFDE) have been reported. With/without a prolonged treatment period, renal tubular acidosis and hypokalemia may occur following ibuprofen overdose. Combiflam® is contraindicated in the third trimester due to risks of fetal harm, including ductus arteriosus constriction and oligohydramnios. Use in the second trimester is discouraged unless absolutely necessary.

Adverse Reactions: *Paracetamol:* thrombocytopenia, neutropenia, leucopenia, erythema, urticaria and rash.

Ibuprofen: Combiflam® Tablets can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection (including bacterial community-acquired pneumonia, serious cutaneous and soft tissue infections and bacterial complications to varicella), symptoms of aseptic meningitis with neck stiffness, headache, nausea, vomiting, fever or consciousness clouding, disturbances to blood formation (anemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis); hypersensitivity reactions with skin rashes and itching, as well as asthma attacks (possibly with drop in blood pressure), severe general hypersensitivity reactions presented as face oedema, swelling of the tongue, swelling of the internal larynx with constriction of the airways, respiratory distress, racing heart, drop in blood pressure up to life-threatening shock; psychotic reactions, depression; central nervous disturbances such as headache, dizziness, sleeplessness, agitation, irritability or tiredness; visual disturbances; tinnitus; palpitations, heart failure, myocardial infarction; arterial hypertension, vasculitis; gastro-intestinal complaints such as pyrosis, abdominal pain, nausea, dyspepsia, vomiting, flatulence, diarrhoea, constipation and slight gastro-intestinal blood losses that may cause anemia in exceptional cases, gastrointestinal ulcers, potentially with bleeding and perforation, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis, esophagitis, pancreatitis, formation of intestinal diaphragm-like strictures, severe pain in the upper abdomen or melaena or hematemesis; hepatic dysfunction, hepatic damage, hepatic failure, acute hepatitis; skin rashes, bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), alopecia. In exceptional cases, severe skin infections and

soft-tissue complications may occur during a varicella infection; kidney-tissue damage (papillary necrosis) and elevated uric acid concentrations in the blood, formation of oedemas, particularly in patients with arterial hypertension or renal insufficiency, nephrotic syndrome, interstitial nephritis that may be accompanied by acute renal insufficiency.

For full prescribing information please contact: Sanofi Consumer Healthcare India Ltd., Unit 1104, 11th Floor, Godrej Two, Pirojshanagar, Eastern Express Highway, Vikhroli East, Mumbai – 400079, India

Updated: January - 2025

Source: 1. CCDS V2.1 (Opella) for Paracetamol dated 16th October 2025.
2. CCDS V11 for Ibuprofen dated 06th March 2025