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

**Abridged Prescribing Information**

**COMBIFLAM® Suspension**
Ibuprofen and Paracetamol Suspension
Anti-inflammatory Analgesic

**Composition**: Each 5ml of Combiflam® Suspension contains Ibuprofen IP 100mg and Paracetamol IP 162.5mg in a flavoured syrup base.
**Therapeutic Indication:** Management of mild to moderate pain and inflammation in conditions such as 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 and Administration:**
Children: If this product is required for more than 3 days in children aged 6 months and above, or if symptoms worsen, a doctor should be consulted. Adults may use the Combiflam® tablets formulation.

**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 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, patients with severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake), 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. 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 and malnutrition and other sources of low glutathione reserves. High anion gap metabolic acidosis (HAGMA) can occur in severely ill patients taking therapeutic doses of paracetamol, especially with prolonged use or when combined with flucloxacillin. Symptoms include rapid deep breathing, drowsiness, nausea, and vomiting. If HAGMA is suspected, stop paracetamol and monitor the patient closely. Urinary 5-oxoproline testing can help confirm pyroglutamic acidosis. Caution in patients with SLE and mixed connective tissue disease for risk of aseptic meningitis or hepatitis, congenital disorder of porphyrin metabolism, 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. Patients with known analgesic intolerance or known bronchial asthma must use after consulting physician. Careful assessment in case of cardiovascular disease 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. Side effects more frequent in elderly patients. Not recommended in women attempting to conceive.
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 of NSAIDs including Combiflam® at about 20 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.

**Adverse Reactions:** *Paracetamol:* Thrombocytopenia, neutropenia, leucopenia, erythema, urticaria and rash.
*Ibuprofen:* Combiflam® 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, diarrhea, 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
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Source: i) CCDS V5 for Paracetamol dated 23rd Jan 2025
ii) CCDS V10 for Ibuprofen dated 08th October 2024