

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

### Abridged Rx 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:

Age group	Dosage
3months – 1year	2-2.5ml three to four times daily
1-4 years	4-4.5ml three to four times daily
4-7 years	4-8ml three to four times daily
7-10 years	8-10ml three to four times daily
10-12 years	8-15ml three to four times daily

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:** Hepatotoxicity 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, glucose-6-phosphate-dehydrogenase deficiency, Gilbert's syndrome, chronic alcohol use including recent cessation of alcohol intake and 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, 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. Ibuprofen may mask signs of an infection (fever, pain, swelling). Not recommended in women attempting to conceive.

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

*Ibuprofen:* Exacerbation of infection-related inflammations (necrotising fasciitis) coinciding with the use of NSAIDs, aseptic meningitis with neck stiffness, headache, nausea, vomiting, fever or consciousness clouding, disturbances to blood formation (anaemia, 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 anaemia in exceptional cases, gastrointestinal ulcers, potentially with bleeding and perforation, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis, oesophagitis, pancreatitis, formation of intestinal diaphragm-like strictures, severe pain in the upper abdomen or melaena or haematemesis; 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 India Ltd.**, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072

Updated on – July 2019

Source: i) CCDS V2 2.0 for Ibuprofen dated July 2019

ii) CCSI V 2.0 for Paracetamol dated 2<sup>nd</sup> March 2017