Abridged Prescribing Information

Paracetamol and Caffeine Tablets I.P.
Combiflam® Plus

COMPOSITION: Each uncoated tablet contains Paracetamol I.P. 650 mg, Caffeine I.P. 50mg, Excipients q.s.

INDICATIONS: For symptomatic relief from mild to moderate pain including, headache, migraine, toothache and musculoskeletal pain (body pain). Combiflam® Plus contains paracetamol, which is an analgesic and antipyretic, and caffeine enhances the pain-relieving activity of paracetamol.

DOSAGE AND ADMINISTRATION: Unless otherwise prescribed by the physician, the following dosages are recommended: Adults and children over 12 years: 1 tablet 3 to 4 times a day every 6 to 8 hours with a minimum gap of 4 hours in a 24 hour period. Do not exceed stated dose. If symptoms persist, seek medical advice. Combiflam® Plus is not recommended in children under 12 years of age. Do not take this medicine more than 3 days without medical advice.

SAFETY RELATED INFORMATION

Contraindications: Patients with hypersensitivity to paracetamol, caffeine or any of the excipients and in patients with severe hepatocellular insufficiency.

Special warnings and precautions:
Related to Paracetamol component: Hepatotoxicity may occur with paracetamol even at therapeutic doses, after short treatment duration and in patients without pre-existing liver dysfunction.
Severe cutaneous adverse reactions (SCARs): Life-threatening cutaneous reactions Stevens-Johnson syndrome (SJS), and Toxic epidermal necrolysis (TEN) have been reported with the use of Combiflam® Plus. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If symptoms or signs of SJS and TEN (e.g. progressive skin rash often with blisters or mucosal lesions) occur, patients should immediately stop Combiflam® Plus treatment and seek medical advice. To avoid the risk of overdose, check that paracetamol is absent from the composition of other medicinal products taken concomitantly. Caution is advised in patients with underlying sensitivity to aspirin and/or to non-steroidal anti-inflammatory drugs (NSAIDs). Combiflam® Plus should be used upon medical advice in patients with mild-to-moderate hepatocellular insufficiency, chronic alcohol use including recent cessation of alcohol intake, low glutathione reserves, glucose-6-phosphate-dehydrogenase deficiency, Gilbert´s syndrome
Related to Caffeine component: Caution is advised in patients with anxiety disorders (risk of enhancement) and arrhythmia (risk of tachycardia or extra systoles enhancement). Excessive intake of caffeine (products with caffeine e.g. coffee, tea, foods, other drugs and beverages) should be avoided while taking this product.
*Related to Caffeine + Paracetamol component***:** Combiflam® Plus should be used upon medical advice in patients with renal impairment

Pregnancy and Lactation: Because of the content of caffeine, Combiflam® Plus is not recommended during pregnancy. Lactation does not usually need to be discontinued if the product is taken for a short time only and in the recommended doses. Lactation should be discontinued in the case of prolonged use or intake of higher doses. Use of this product during lactation is recommended under medical supervision.

For full prescribing information, please contact: Sanofi India Limited, Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072

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Source:
1. Ref: Paracetamol + caffeine CCDS v3 LRC dated 08th Jul 2021.
2. Product Information Leaflet - Crocin Pain Relief (https://india-consumer.gsk.com/media/861691/crocin-pain-relief.pdf - as assessed on 03rd November 2020)
3. Final Guidance Document_ Acetaminophen Labelling Standard_Health Canada