Abridged Prescribing Information

Paracetamol and Caffeine Tablets I.P.
Novalgin® NU

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). Novalgin® NU 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. Novalgin® NU 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 Novalgin® NU. 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 Novalgin® NU 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). Novalgin® NU should be used upon medical advice in patients with some pre-disposing factors like mild-to-moderate hepatocellular insufficiency, Sever renal impairment and sepsis, chronic alcohol use including recent cessation of alcohol intake, Malnutrition and other sources of low glutathione reserves, glucose-6-phosphate-dehydrogenase deficiency, Gilbert´s syndrome.
High anion gap metabolic acidosis (HAGMA) from pyroglutamic acidosis has been reported in severely ill patients with risk factors treated long-term with therapeutic paracetamol or paracetamol plus flucloxacillin. Symptoms include deep rapid breathing, drowsiness, nausea, and vomiting. Discontinue paracetamol and monitor closely if HAGMA symptoms occur. Urinary 5-oxoproline measurement can help identify pyroglutamic acidosis in high-risk patients.
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***:** Novalgin® NU should be used upon medical advice in patients with renal impairment

Pregnancy and Lactation: Because of the content of caffeine, Novalgin® NU 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 Consumer Healthcare India Limited, Unit 1104, 11th Floor, Godrej Two, Pirojshanagar, Eastern Express Highway, Vikhroli East, Mumbai – 400079. Maharashtra, India

Updated: October 2025

Source:

1. Paracetamol + caffeine CCDS v4 LRC dated 23rd January 2025.
2. Product Information Leaflet - Crocin Pain Relief (https://india-consumer.gsk.com/media/861691/crocin-pain-relief.pdf - as assessed on 25th Aug 2021)
3. Final Guidance Document_ Acetaminophen Labelling Standard_Health Canada