

NIMUNICE P

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for NIMUNICE P [Nimesulide and Paracetamol Tablets]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Nimesulide:* Nimesulide only weakly inhibits prostaglandin synthesis and appears to exert its effects through various mechanisms. It inhibits the release of oxidants from activated neutrophils and has a scavenging effect on hypochlorous acid without affecting neutrophil function. *Paracetamol:* Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent, through a peripheral action by blocking pain impulse generation.

INDICATIONS: It is indicated for the short-term use in fever, acute painful and inflammatory conditions such as headache, toothache, backache, rheumatic and muscle pains, dysmenorrhoea, sore throat in adults.

DOSAGE AND ADMINISTRATION: Nimesulide and Paracetamol tablets should be used for the shortest possible duration, as required by the clinical situation. Moreover, undesirable effects may be minimised by using the minimum effective dose for the shortest duration necessary to control symptoms. Taking more than the daily dose of paracetamol may cause serious liver damage or allergic reaction (e.g. swelling of face, mouth and throat, difficulty in breathing, itching or rash). Use of Nimesulide should ordinarily be restricted to 10 days. *Adults:* Tablets or Granules: one 100 mg / 325 mg tablet twice a day after meals. *Elderly:* In elderly patients there is no need to reduce the daily dosage. *Children (< 12 years):* 100 mg / 325 mg tablet is contraindicated in these patients. For oral use.

CONTRAINDICATION: Hypersensitivity to nimesulide or to any of the excipients, history of hypersensitivity reactions such as bronchospasm, rhinitis, urticaria, or nasal polyps in response to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs, history of hepatotoxic reactions to nimesulide, concomitant exposure to other potentially hepatotoxic substances, alcoholism or drug addiction, history of gastrointestinal bleeding or perforation related to previous NSAID therapy, active or recurrent peptic ulcer or haemorrhage with two or more distinct episodes of proven ulceration or bleeding, cerebrovascular bleeding or other active bleeding or bleeding disorders, severe coagulation disorders, and severe heart failure.

WARNINGS & PRECAUTIONS: Nimesulide should be used only as a second line drug, only after exhausting first line options. Nimesulide should not be used in pregnant, lactating and women planning for pregnancy. Nimesulide should not be used in patients with renal and hepatic impairment and also should not be co-administered with other hepatotoxic and renal toxic drugs. Nimesulide and paracetamol should be avoided in both pregnant (especially last trimester of pregnancy) and breastfeeding women, as it may pass the milk affecting the baby. Patients with heart diseases and recent stroke (bleeding in the brain) should not take nimesulide and paracetamol as a substitute for aspirin. It should not be given to children (below 12 years) with symptoms of fever and chills or suffering from influenza (flu) or chickenpox.

DRUG INTERACTIONS: Nimesulide and paracetamol is shown to interact with various drugs. Some of them include lithium, anticancer/antimetabolites (methotrexate), blood thinner or anticoagulant (warfarin, coumadin, aspirin), blood pressure or heart medicine, nausea medicine (metoclopramide, domperidone), diuretic/water pills (thiazides, furosemide), steroid medicine (prednisone), quinolones antibiotics (ciprofloxacin), respiratory medicines (theophyllines, ephedrine), immune system affecting medicine (cyclosporine), cholesterol-reducing medicine (cholestyramine) and antidepressants (duloxetine). These drugs may affect the working of Nimesulide + Paracetamol and may alter its efficacy. Excessive intake of alcoholic beverages, caffeine-containing food or drinks like coffee, tea, chocolate, and some fizzy drinks should be avoided while taking nimesulide and paracetamol. Taking

together may lead to drowsiness, dizziness and sleepiness. Nimesulide and paracetamol should not recommend for people having bleeding disorders, like haemophilia, von Willebrand disease, or low blood platelets. Besides this, it should not be given to children suffering from influenza (flu) or chickenpox. It should also be avoided in case of the presence of gastric or duodenal ulcers.

ADVERSE REACTIONS: Feeling of sickness, skin redness, allergic reactions, shortness of breath, swollen facial features, and liver damage.

MARKETED BY:

TORRENT
PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)