

NIMUNICE

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

Abbreviated Prescribing information for NIMUNICE [Nimesulide Tablet 100 mg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: 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.

INDICATIONS: It is indicated for the treatment of inflammatory condition including joint disorder such as rheumatoid arthritis, post traumatic and post operative painful condition and fever.

DOSAGE AND ADMINISTRATION: Nimesulide 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. Use of Nimesulide should ordinarily be restricted to 10 days. *Adults:* Tablets or Granules: one 100mg tablet twice a day after meals. *Elderly:* In elderly patients there is no need to reduce the daily dosage. *Children:* (< 12 years):100mg tablets is contraindicated in these patients. For oral use.

CONTRAINDICATION: Hypersensitivity to nimesulide or to any of the excipients, history of hypersensitivity reactions (e.g. bronchospasm, rhinitis, urticaria, 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, drug addiction, history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy, active, or history of recurrent peptic ulcer / haemorrhage (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. The use of Nimesulide 100mg tablets with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. In addition, patients should be advised to refrain from other concomitant analgesics. Undesirable effects may be minimised by using the minimum effective dose for the shortest duration necessary to control symptoms. Treatment should be discontinued if no benefit is seen.

DRUG INTERACTIONS: *Other non-steroidal anti-inflammatory drugs (NSAIDs):* The combined use of Nimesulide with other non-steroidal anti-inflammatory drugs, including acetylsalicylic acid given at anti-inflammatory doses ($\geq 1\text{g}$ as single intake or $\geq 3\text{g}$ as total daily amount) is not recommended. *Corticosteroids:* Increased risk of gastrointestinal ulceration or bleeding. *Anti-coagulants:* NSAIDs may enhance the effects of anti-coagulants, such as warfarin.

ADVERSE REACTIONS: Small increased risk of arterial thrombotic events (for example myocardial infarction or stroke), oedema, hypertension, cardiac failure, bullous reactions, Stevens Johnson Syndrome and Toxic Epidermal Necrolysis.

MARKETED BY:

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IN/Nimunice 100 mg/Feb-2026/01/ABPI

(Additional information is available on request)