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

NIMUNICE

WARNING

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.

1. Generic Name

Nimesulide Tablet 100 mg

2. Qualitative and quantitative Composition:

Each uncoated tablet contains:

Nimesulide B.P. ……100 mg

Excipients ……...q.s.

The List of Excipients used are Maize Starch, Polyvinylpyrrolidone, Dicalcium Phosphate, Methyl Paraben, Propyl Paraben, Magnesium Stearate, Talc, Sodium starch Glycolate, Colloidal silicon Dioxide.

3. Dosage form and strength

Dosage form: Uncoated tablets

Strength: Nimesulide 100 mg

4. Clinical particulars

4.1. Therapeutic indication

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.

4.2. Posology and method of administration

Posology

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. If longer clinical use is warranted, liver function test should be assessed periodically.

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.

Acute pain:

An initial dose is 50-100 mg depending on the intensity of pain. 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.

Children

Nimesulide capsules are not suitable for children below the age of 12 years.

Renal insufficiency/Dialysis and hepatic impairment

Impaired renal function: On the basis of pharmacokinetics, no dosage adjustment is necessary in patients with mild to moderate renal impairment (creatinine clearance of 30-80 ml/min).

Method of administration

For oral use.

4.3. Contraindications

- 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
- Severe heart failure

4.4. Special warnings and precautions for use

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.

4.5. Drugs interactions

Pharmacodynamic 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 (≥ 1g as single intake or ≥ 3g 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.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

The use of nimesulide 100 mg tablets is contraindicated in the third trimester of pregnancy.

Like other NSAIDs nimesulide 100 mg tablets is not recommended in women attempting to conceive.

Inhibition of prostaglandin synthesis may have a negative impact on pregnancy and/or embryonic/fetal development.

4.7. Effects on ability to drive and use machines

No studies on the effect of nimesulide containing medicinal products on the ability to drive or use machines have been performed. However, patients who experience dizziness, vertigo, or somnolence after receiving nimesulide should refrain from driving or operating machines.

4.8. Undesirable effects

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Oedema, hypertension, and cardiac failure have been reported in association with NSAID treatment. Very rare cases of bullous reactions including Stevens Johnson Syndrome and Toxic Epidermal Necrolysis have been reported.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com.

4.9. Overdose

Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur.

Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose. Patients should be managed by symptomatic and supportive care following an NSAID overdose.

5. Pharmacological properties

5.1. 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.

5.2. Pharmacodynamic properties

Nimesulide is a non-steroidal anti-inflammatory drug with analgesic and antipyretic properties which acts as an inhibitor of prostaglandin synthesis enzyme cyclooxygenase.

5.3. Pharmacokinetic properties

Tablets of nimesulide is well absorbed when given per O.S. After a single dose of 100 mg nimesulide a peak plasma level of 3-4 mg/l is reached in adults after 2-3 hours.

AUC = 20 - 35 mg h/l. No statistically significant difference has been found between these figures and those seen after 100mg given twice daily for 7 days.

Paediatric population:

Children (< 12 years):100mg Tablets is contraindicated in these patients.

Adolescents (from 12 to 18 years): On the basis of the kinetic profile in adults and on the pharmacodynamic characteristics of nimesulide, no dosage adjustment in these patients is necessary.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

Preclinical data reveal no special hazards for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

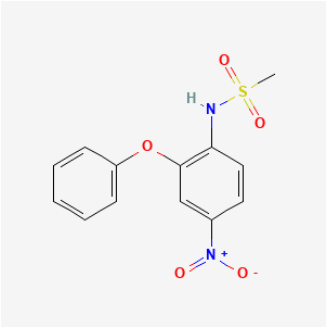
In repeated dose toxicity studies, nimesulide showed gastrointestinal, renal and hepatic toxicity.

In reproductive toxicity studies, embryogenic and teratogenic effects (skeletal malformations, dilatation of cerebral ventricles) were observed in rabbits, but not in rats, at maternally non-toxic dose levels. In rats, increased mortality of offspring was observed in the early postnatal period and nimesulide showed adverse effects on fertility.

7. Description

Nimesulide

Nimesulide is N-(4-nitro-2-phenoxyphenyl)methanesulfonamide. The empirical formula is $C_{13}H_{12}N_2O_5S$ and molecular weight is 308.31 g/mol. The chemical structure is



Nimunice

Nimunice is yellow coloured, round shape biconvex plain on both side uncoated tablets. The list of excipients used are Maize Starch, Polyvinylpyrrolidone, Dicalcium Phosphate, Methyl Paraben, Propyl Paraben, Magnesium Stearate, Talc, Sodium starch Glycolate, Colloidal silicon Dioxide.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than date of expiry.

8.3. Packaging information

Nimunice is available in pack of 10 Tablets.

8.4. Storage and handing instructions

Store protected from light & moisture at a temperature not exceeding 30°C.

Keep the medicines out of reach of children.

Do not use in children below 12 years of age.

Use of Nimesulide should ordinarily be restricted to 10 days. If longer clinical use is warranted, liver function test should be assessed periodically.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10. Details of manufacturer

Lucent Biotech Ltd. (Unit-II)

(An ISO 9001:2015 & WHO GMP Certified Co.)

K-165/3, Nalhera Anantpur, Roorkee,

Dist.- Haridwar (Uttarakhand)

11. Details of permission or licence number with date

Mfg. Licence No: 43/UA/2016 Issue date: 18.09.2019

12. Date of revision

NA

MARKETED BY

TORRENT PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/Nimunice 100 mg/FEB-2026/01/PI