# NIMUTAB®

Tablets

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## Composition:

Each tablet contains

Nimesulide 100mg

## Pharmacokinetic properties:

After administration of nimesulide 50-200 mg to healthy adult volunteers, peak serum concentrations of 1.98-9.85 mg/L are achieved within 1.22-3.17 hours. Absorption is nearly complete and concomitant administration of food may decrease the rate, but not the extent of absorption of Nimesulide. The drug is extensively bound (99%) to plasma proteins and has an estimated apparent volume of distribution of 0.19-0.35 l/kg. Nimesulide undergoes extensive metabolism and metabolites are excreted mainly in urine. The 4-hydroxynimesulide appears to contribute to the anti-inflammatory activity of nimesulide. The peak concentrations of 4- hydroxynimesulide range from 0.84-3.03 mg/l and are attained within 2.61-5.33 hours after administration. The elimination half-life of 4-hydroxy-nimesulide ranges from 2.89-4.78 hours and is generally similar to or slightly higher than that of the parent compound. The pharmacokinetic profile of nimesulide is not significantly altered in children, elderly volunteers and patients with moderately impaired renal function (creatinine clearance 30-80 ml/min).

## Mechanism of Action

NIMUTAB is a non-steroidal anti-inflammatory drug (NSAID) and possess analgesic, antipyretic and anti-inflammatory properties. It acts by following actions:

- Inhibiting prostaglandin biosynthesis.
- inhibition of generation of superoxide anions by polymorphonuclear leucocytes;
- inhibition of platelet activating factor synthesis;
- Prevention of bradykinin/cytokine induced hyperalgesia. In addition, NIMUTAB also
- scavenge hypochlorous acid;
- block histamine release
- prevent cartilage damage by inhibition of metalloprotease synthesis
- Inhibiting the formation of free O2 radicals without influencing chemotaxis and phagocytosis.

## Indication:

NIMUTAB is indicated in:

- Fever
- Pain

**Contraindication:**

NIMUTAB should not be used in those patients who have previously shown hypersensitivity to nimesulide, those with active peptic ulcer, severe or moderate hepatic insufficiency and severe renal dysfunction

**Drug Interaction:**

NIMUTAB is highly protein bound and might be expected to displace other protein bound drugs. However, no clinically significant interactions have been observed on concomitant administration of nimesulide with furosemide, warfarin, digoxin, theophylline, glibenclamide, cimetidine and antacids

**Adverse effects:**

NIMUTAB is generally well tolerated. Heartburn, nausea, gastralgia, allergic skin rashes, headache and vertigo have occasionally been reported with nimesulide. These side effects are generally mild and transient, and rarely require the interruption of treatment.

**Warnings and Precautions:**

NIMUTAB administration should be closely supervised in patients with hypersensitivity to aspirin and other NSAIDs. The potential exists for cross sensitivity to aspirin and other NSAIDs.

**Use in special population:**

1. **Pediatric:** safety and efficacy of oral use of nimesulide in children has not been evaluated.
2. **Geriatric: Use with caution.**
3. **Liver impairment:** Use with caution.
4. **Renal failure:** Use with caution.
5. **Pregnancy and lactation:** As for the NSAIDs, the use of NIMUTAB during pregnancy is not recommended. NIMUTAB should not be used at the third trimester of pregnancy as NSAIDs are known to induce closure of the ductus arteriosus. It is not known whether nimesulide is secreted in breast milk. Therefore, NIMUTAB should not be administered to nursing mothers.

**Dosage:**

As directed by physician.

**Presentation:**

NIMUTAB is available in a blister of 10 tablets

**Storage and handling:**

Store in cool and dry palce.