Modact-IR
(Nimesulide)

موڈایکٹ۔آئی آر
(نائیمسولائیڈ)

COMPOSITION:
Each tablet contains:
Nimesulide (B.P.).....100 mg
Product Complies Platinum Specs.

PHARMACOLOGY:
Nimesulide is a nonsteroidal anti-inflammatory drug(NSAID) that selectively inhibits cyclooxygenases 2, the inducible form of the enzyme found almost exclusively in inflammatory tissues but largely devoid of physiological activity in healthy tissues, in which cyclooxygenease 1 plays important regulating roles(particularly gastric and renal physiological control). Most NSAIDs block both cyclooxygenase 1 and cyclooxygenase 2, and as a result, they impair the production of prostaglandins critical to gastric mucosal protection and renal function, which results in clinically significant adverse reactions, especially regarding the risk of gastrotoxicity. Nimesulide is the leading molecule of a new chemical class, the sulphonanilides, which has shown a significant inhibitory selection towards cyclooxygenase 2 without affecting cyclooxygenase 1. This results in equivalent efficacy against pain and inflammation but with a better safety profile, particularly at the gastrointestinal level. The anti-inflammatory, analgesic and antipyretic activities of Nimesulide have been demonstrated in a number of experimental models and in numerous clinical trials. Nimesulide exhibit potency similar to or greater than that of Indomethacin, Diclofenac, Piroxicam and Ibuprofen, in guinea-pigs and adjuvant arthiritis in rats. The analgesic potency of Nimesulide was similar to that of Ibuprofen and less than that of Indomethacin in an acetic acid writhing test in rats. Nimesulide has shown superior antipyretic potency to Indomethacin, Ibuprofen, Aspirin and Paracetamol (Acetaminophen) in rats with yeast- induced fever.

Nimesulide appears to exert its therapeutic effects through a variety of mechanisms:-

- Selective inhibition of Cox-2
- Inhibition of superoxide anions from stimulated polymorphs
- Inhibition of platelet activating factor synthesis
- Prevention of bradykinin/Cytokines stimulation of nerves
- Scavenging of histamine release
- Prevention of cartilage damaged by inhibition of metalloprotease synthesis

PHARMACOKINETICS:
On oral administration of Nimesulide 50-200 mg tablets to healthy volunteers, peak serum concentration of 1.98 to 9.85 mg/L are achieved within 1.22 to 3.17 hours. Oral absorption of Nimesulide is nearly complete. Concomitant administration of food may decreases the rate but not the extent of absorption of Nimesulide. Plasma binding was high (99%) and the apparent volume of distribution ranged from 0.19 to 0.35 L/kg. Nimesulide is extensively metabolized to several metabolites which are excreted mainly in the urine (70%) and in feaces (20%).

In patients with moderately impaired renal function (creatinie clearance 1.8 to 4.8 L/h, (30 to 80 ml/min), also in children and elderly volunteers, the pharmacokinetic profile of Nimesulide is not significantly altered. In patients with moderate renal impairment, slight accumulation of 4-hydroxy Nimesulide was noted, however, the clinical significance of this finding is unknown.

In children, compared with values for adult healthy volunteers, t_{max} and $t^{1/2}$ B values were similar for the granule formulation but lower for the suppository formulation suggesting a faster absorption and elimination of the suppository.

WHAT (Nimesulide) IS AND WHAT IT IS USED FOR.
(Nimesulide) is non-steroidal anti-inflammatory drug (NSAID) with pain-killing properites. It is used for the treatment of acute pain and for the treatment of period pains.

INDICATION:
Nimesulide (Modact-IR) is indicated in the treatment of acute pain and primary dysmenorrhoea.

Nimesulide should only be prescribed as second line treatment . The decision to prescribed nimesulide should be based on assesment of the individual patient's overall risks.

UNDESIRABLE EFFECTS:
Gastrointestinal disorders
uncommon: Gastrointestinal bleeding, Duodenal ulcer and perforation, Gastric ulcer and perforation.

Hepato-biliary disorders
Common: Hepatic enzymes increased.

CONTRA-INDICATIONS:
Peptic ulcer, known hypersensitivity to the active substance, acetylsalicylic acid, or other prostaglandin synthetase inhibiting drugs.

PRECAUTIONS:
Symptoms/history of gastro-intestinal disease, impaired hepatic, cardiac or renal function, pregnancy and lactation and porphyria. Caution in the elderly patients with extracellular volume depletion from any cause. Patients on diuretics, anti-coagulants, or antidiabetics. If in exceptional cases prolonged treatment proves necessary, periodic monitoring of liver function should be carried out and blood counts are recommended.

DRUG INTERATCTIONS:
Clinically important interactions involving interference with drug metabolism have been described with Nimesulide.

DOSAGE AND ADMINISTARATION:
Adults: Usual oral dose of Nimesulide in adults is 100 mg tablets twice day.

Recommendation: Should not be used more than 15 days. (According to EMA).

POSSIBLE SIDE EFFECTS
Side effect that may occur with (Nimesulide) are:

Uncommon: Bleeding from stomach or bowel; duodenal or stomach ulcers and burst ulcers.

PRESENTATION: Blister pack of 10 tablets

Store below 30°C in a dry place, protect from light. To be dispensed on the prescription of a registered medical practitioner only. Keep out of the reach of children.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں،
روشنی سے بچائیں۔صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔
بچوں کی پہنچ سے دُور رکھیں۔

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