DOLOTEC
(Naproxen Sodium)

ڈولوٹیک ۵۵۰ ملی گرام گولیاں
(نیپروکسن سوڈیم)

550 mg Tablets

Nonsteroidal anti-inflammatory agent

COMPOSITION
Each film coated tablet contains:
Naproxen Sodium (USP) ..... 550 mg
Product Complies USP Specs.

CHEMICAL CLASSIFICATION
Propionic acid derivative.

PROPERTIES AND EFFECTS
DOLOTEC (Naproxen Sodium) has been shown to have striking anti-inflammatory properties when tested in human clinical studies. In addition, it has marked analgesic & anti-pyretic actions.

PHARMACOKINETICS
Absorption : DOLOTEC (Naproxen Sodium) is rapidly and completely absorbed from the gastrointestinal tract after oral administration. Concomitant administration of food can delay the absorption of Naproxen Sodium, but does not affect its extent. After administration of Naproxen Sodium, peak plasma levels are attained in approximately 1 hour.
Distribution: DOLOTEC (Naproxen Sodium) has a volume of distribution of 0.16 l/kg. At therapeutic levels Naproxen Sodium is greater than 99% albumin-bound. Its plasma half life is approximately 13 hours.
DOLOTEC (Naproxen Sodium) enters synovial fluid, crosses the placenta and has been found in the milk of lactating mothers at a concentration approximately. 1% of that found in plasma.
Metabolism: Naproxen Sodium is extensively metabolised in the liver.
Elimination: The preferred route of excretion is via the urine, only 1% of the dose excreted in the feces.
Renal Impairment: As Naproxen Sodium is primarily excreted by the kidney, there is the potential risk for accumulation in renal impaired patients.
Children: The pharmacokinetic profile of Naproxen in children aged 5-16 years is similar to that in adults although the clearance is generally higher in children than in adults. Pharmacokinetic studies of Naproxen were not performed in children less than 5 years of age.

INDICATIONS
DOLOTEC Tablet (Naproxen Sodium) is indicated for:
- Severe Dental pain
- Dental pain due to dental extractions and surgery

DOSAGE AND ADMINISTRATION
DOLOTEC Tablet Dose in Adults:
The recommended dose of DOLOTEC Tablet 550 mg in conditions like severe dental pain. pain due to dental extractions and surgery is twice daily (mornning & evening) or a single dose of 550 mg to 1100 mg given in the mornning or evening. However for long term administration the dose may be adjusted depending on the clinical response of the patient. A lower daily dose may suffice for long term administration.
Dose in children:
Safety and effectiveness in children below the age of 5 years have not been established.
Analgesic and antipyretic use in children — Naproxen Sodium 11 mg/kg as an initial dose followed byNaproxen Sodium 2.75 - 5.5 mg/kg at 8 hour intervals. The daily dosage should not exceed Naproxen Sodium 16.5 mg/kg/day after first day.

CONTRAINDICATIONS
Naproxen sodium is contraindicated in patients who are allergic to any of its components. It is also contrainidicated in patients in whom aspirin or any other non-steroidal anti-inflammatory drugs induce the syndrome of asthma, rhinitis and nasal polyps. Naproxen Sodium should not be administrated to patients presenting erythema or pruritis or having psoriasis. Naproxen Sodium should not be administrated to patients with active peptic ulcer.

SIDE-EFFECTS
Like other NSAIDs, the undesirable effects observed in the clinical use of DOLOTEC (Naproxen Sodium) may be:
GastroIntestInal: Constipation, heartburn, abdominal pain and nausea.
Central Nervous System: Headache, dizziness and drowsiness.
Dermatological: Itching (pruritis), skin eruption and ecchymoses.
Special Senses: Tinnitus.
Cardiovascular: Oedema and dyspnoea.
General: Thirst.

PRECAUTIONS AND WARNINGS
Gastrointestinal ulceration, bleeding and perforation may occur in patients treated with NSAIDs including Naproxen Sodium.

PREGNANCY
As a general rule no drug should be administrated during the first trimester and or during the last month of pregnancy.
Naproxen containing products are not recommended in labour and delivery because, through its prostaglandin synthesis inhibitory effect, it may adversely affect foetal circulation and inhibit uterine contractions, thus increasing the risk of uterine haemorrhage.
DOLOTEC (Naproxen Sodium) should be used during pregnancy only if the potential benefit justifies the potential risk to uterus.

NURSING MOTHER
Naproxen sodium has been found in milk of lactating women at a concentration of approximately 1% of that found in plasma. Because of the possible adverse effects of prostaglandin-inhibiting drugs on neonates, use in nursing mothers is not recommended.

OVERDOSAGE
Significant overdosage may be characterized by drowsiness, heartburn, indigestion, nausea or vomiting. When a patient ingests a large number of tablets, the stomach may be emptied and usual supportive measures employed.
In animals 0.5 g/kg of activated charcoal was effective in reducing plasma levels of Naproxen.

PRESENTATION
DOLOTEC Tablet: Naproxen Sodium 550 mg in blister pack of 2 x 10 tablets.

STORAGE
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 روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

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