Naproxen sodium tablets-film-coated

Each tablet film-coated contains:
Naproxen sodium .....550 mg

DRUG DESCRIPTION :

NAPROXEN SODIUM Tablets contain naproxen sodium, a member of the arylacetic acid group of nonsteroidal anti-inflammatory drugs (NSAIDs). NAPROXEN SODIUM Tablets use the proprietary IPDAS (Intestinal Protective Drug Absorption System) technology. It is a rapidly disintegrating tablet system combining an immediate release component and a sustained release component of microparticles that are widely dispersed, allowing absorption of the active ingredient throughout the gastrointestinal (GI) tract, maintaining blood levels over 24 hours. The chemical name for naproxen sodium is 2-naphthaleneacetic acid, 6-methoxy-a-methyl-sodium salt, (S)- with the

Naproxen sodium
Molecular Formula: C14H13NaO3 Molecular Weight: 252.24

Naproxen sodium is an odorless crystalline powder, white to creamy in color. It is soluble in methanol and water. NAPROXEN SODIUM Tablets contain 412.5 mg or 550 mg of naproxen sodium, equivalent to 375 mg and 500 mg of naproxen and 37.5 mg and 50 mg sodium respectively. Each NAPROXEN SODIUM Tablet also contains the following inactive ingredients: ammoniomethacrylate copolymer Type A, ammo-niomethacrylate copolymer Type B, citric acid, crospovidone, magnesium stearate, methacrylic acid copolymer Type A, microcrystalline cellulose, povidone, and talc. The tablet coating contains hydrox-ypropyl methylcellulose, polyethylene glycol, and titanium dioxide.

INDICATIONS :

Carefully consider the potential benefits and risks of NAPROXEN SODIUM Tablets and other treatment options before deciding to use NAPROXEN SODIUM Tablets. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see WARNINGS).

NAPROXEN SODIUM Tablets are indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, tendinitis, bursitis and acute gout. It is also indicated in the relief of mild to moderate pain and the treatment of primary dysmenorrhea.

DOSAGE AND ADMINISTRATION :

Carefully consider the potential benefits and risks of NAPROXEN SODIUM and other treatment options before deciding to use NAPROXEN SODIUM . Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see WARNINGS).

After observing the response to initial therapy with NAPROXEN SODIUM , the dose and frequency should be adjusted to suit an individual patient's needs

SIDE EFFECTS :

As with all drugs in this class, the frequency and severity of adverse events depends on several factors: the dose of the drug and duration of treatment; the age, the sex, physical condition of the patient; any concurrent medical diagnoses or individual risk factors. The following adverse reactions are divided into three parts based on frequency and whether or not the possibility exists of a causal relationship between drug usage and these adverse events. In those reactions listed as "Probable Causal Relationship" there is at least one case for each adverse reaction where there is evidence to suggest that there is a causal relationship between drug usage and the reported event.

The adverse reactions reported were based on the results from two double-blind controlled clinical trials of three months duration with an additional nine month open-label extension. A total of 542 patients received NAPROXEN SODIUM Tablets either in the double-blind period or in the nine month open-label extension. Of these 542 patients, 232 received NAPROXEN SODIUM Tablets, 167 were initially treated with Naproxen and 143 were initially treated with placebo. Adverse reactions reported by patients who received NAPROXEN SODIUM Tablets are shown by body system. Those adverse reactions observed with naproxen but not reported in controlled trials with NAPROXEN SODIUM Tablets are italicized.

The most frequent adverse events from the double-blind and open-label clinical trials were headache (15%), followed by dyspepsia (14%), and flu syndrome (10%). The incidence of other adverse events occurring in 3% - 9% of the patients are marked with an asterisk.

- **OVERDOSE :**

Significant naproxen overdosage may be characterized by drowsiness, heartburn, indigestion, nausea or vomiting. Because naproxen sodium may be rapidly absorbed, high and early blood levels should be anticipated. A few patients have experienced seizures, but it is not clear whether or not these were drug-related. It is not known what dose of the drug would be life threatening.

The oral LD50 of the drug is 500 mg/kg in rats, 1200 mg/kg in mice, 4000 mg/kg in hamsters and greater than 1000 mg/kg in dogs. In animals 0.5 g/kg of activated charcoal was effective in reducing plasma levels of naproxen. Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Hemodialysis does not decrease the plasma concentration of naproxen because of the high degree of its protein binding. Emesis and/or activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic carthartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose. Forced diuresis, alkalinization of urine or hemoperfusion may not be useful due to high protein binding.

DISLAIMER

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.
www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.

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