Rapid Analgesic /
Anti-inflammatory agent

ZYNAL® Tablets

Naproxen sodium 275mg

Zynal (Naproxen sodium) is a non-steroidal anti-inflammatory drug with analgesic and antipyretic properties. The sodium salt of naproxen has been developed as an analgesic because it is more rapidly absorbed. Naproxen anion inhibits prostaglandin synthesis but beyond this its mode of action is unknown. Zynal is rapidly and completely absorbed from the gastrointestinal tract. After administration of Zynal, peak plasma levels of naproxen anion are attained at 1~2 hours with steady-state conditions normally achieved after 4~5 doses. The mean biological half-life of the anion in humans is approximately 13 hours.

■ Composition :

Each tablet contains Naproxen sodium
(sodium salt of (+)-6-methoxy-α-methyl-2- naphthaleneacetic acid : USP) 275mg.

■ Indications :

Zynal is indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, tendinitis, bursitis, acute gout, and skeletal-muscle disorder. It is also indicated in the relief of mild to severe pain after operation or dental extraction and for the treatment of primary dysmenorrhea.

■ Dosage & Administration :

1. For mild to severe pain after operation or dental extraction, skeletal-muscle pain, acute tendinitis, bursitis, and primary dysmenorrhea :
   The recommended starting dose is 2 tablets, followed by 1 tablet every 6 to 8 hours, as required. The total daily dose should not exceed 5 tablets.
2. For rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis :
   The recommended dose in adults is 1~2 tablets, twice daily(morning and evening).
3. For acute gout :
   The recommended starting dose is 3 tablets, followed by 1 tablet every 8 hours until the attack has subsided.
4. For migraine :
   The recommended starting dose is 3 tablets, followed by 1~2 tablets per day, as required. The total daily dose should not exceed 5 tablets.

■ Adverse Reactions :

The following additional occurrences have been reported with Zynal but a causal relationship to Zynal has not been established :
abdominal discomfort, epigastric distress, headache, thrombocytopenia, dizziness.

■ Warnings :

Peptic ulcerations and gastrointestinal bleeding have been reported in patients receiving non-steroidal anti-inflammatory drugs, including Naproxen sodium. When the drug is given to patients with a history of gastrointestinal tract disease, it should be given under careful supervision.

■ Contraindications :

The drug is contraindicated in patients who have had allergic reactions to Naproxen sodium.
It is also contraindicated in patients in whom aspirin or other nonsteroidal anti-inflammatory/ analgesic drugs induce the symptoms of asthma, rhinitis, and nasal polyps.

■ Use in Pregnancy :

Use of NSAIDs at about 20 weeks gestation or later in pregnancy may cause foetal renal dysfunction leading to oligohydramnios and in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation.

Oligohydramnios is often, but not always, reversible with treatment discontinuation.
As with other drugs of this type, Zynal produces delay in parturition animals and also effects the human fetal cardiovascular system (closure of the ductus arteriosus). Therefore, the drug should not be used during pregnancy unless clearly needed.
The use of Zynal in pregnancy requires cautious balancing of possible benefits against the potential risks to the mother and fetus, especially in the first and third trimesters.
Naproxen has been found in the milk of lactating mothers.
The use of Zynal should therefore be avoided in patients who are breast feeding.

■ **Drug Interactions :**

Due to the high plasma protein binding of Naproxen, patients simultaneously receiving hydantoins, anticoagulants or a highly protein-bound sulphonamide should be observed for signs of overdosage of these drugs. Interactions have not been observed in clinical studies with Zynal and anti-coagulants or sulphonylureas, but caution is advised, nonetheless, since interaction has been seen with other non-steroidal agents of this class.
The natriuretic effect of furosemide has been reported to be inhibited by some drugs of this class.
Inhibition of renal lithium clearance leading to an increase in plasma lithium concentration has been reported also.
Zynal and other non-steroidal anti-inflammatory drugs can reduce the anti-hypertensive effect of propranolol and other beta-blockers.
Probenecid given concurrently increases naproxen plasma levels and extends its plasma half-life significantly.
Concomitant administration of naproxen and methotrexate should be done with caution, because naproxen has been reported among other non-steroidal anti-inflammatory drugs to reduce the tubular secretion of methotrexate in an animal model, and thus possibly enhance its toxicity.
It is suggested that Zynal therapy be temporarily discontinued 48 hours before adrenal function tests are performed because Zynal may artificially interfere with some tests for 17-ketogenic steroids.
Similarly, naproxen may interfere with some urinary assays of 5-hydroxyindoleacetic acid.

■ **Storage :** Store in a cool, dry and dark place (Shelf life : 3 Years)

Keep out of reach of children.

Manufactured by
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SEOUL, KOREA

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