

Sonap[®]

Naproxen Sodium USP

Composition

Sonap[®] 250 tablet: Each enteric coated tablet contains Naproxen Sodium USP equivalent to Naproxen USP 250 mg.

Sonap[®] 500 tablet: Each enteric coated tablet contains Naproxen Sodium USP equivalent to Naproxen USP 500 mg.

Sonap[®] 500 Suppository: Each suppository contains Naproxen Sodium USP equivalent to Naproxen USP 500 mg.

Sonap[®] Gel: Each gm gel contains 100 mg Naproxen USP.

Pharmacology

Sonap[®] (Naproxen Sodium) is a Non-Steroidal Anti-inflammatory agent. The drug exhibits anti-inflammatory, analgesic, and antipyretic activity by inhibiting prostaglandin synthesis. Both Naproxen and Naproxen Sodium (Sonap) are completely absorbed from the GIT but the peak plasma concentration is attained about 1-2 hours after ingestion of Naproxen Sodium (Sonap) whereas that takes 2-4 hours after ingestion of Naproxen.

Indication

Naproxen is indicated for the relief of symptoms of rheumatoid arthritis, both of acute flares and long term management of the disease. It is also used in the diseases of rheumatoid osteoarthritis (degenerative arthritis), ankylosing spondylitis, juvenile rheumatoid arthritis, tendinitis, bursitis, acute gout, acute musculoskeletal disorders (such as sprains, direct trauma and fibrositis), migraine and dysmenorrhoea.

Dosage & Administration

Tablet & Suppository:

Rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis — 250 to 500 mg twice daily. May be increased to 1.50 gm for limiting periods. Morning and evening doses do not have to be equal, and use of the drug more frequently than twice daily is not necessary. Symptomatic arthritis improvement usually begins in 2 weeks, if no improvement is seen, consider a trial for 2 more weeks.

Mild to moderate pain, primary dysmenorrhoea, acute tendinitis, bursitis, and dysmenorrhoea — 500 mg initially, followed by 250 mg every 6 to 8 hours as required. Do not exceed a 1.375 gm total daily dose.

Acute gout — 750 mg, then 250 mg every 8 hours until attack subsides.

Juvenile arthritis (children over 5 years) — 10 mg/kg daily in two divided doses is recommended.

Gel:

Sonap[®] gel is to be applied 2-6 times a day as required and is not recommended for use in children.

Precaution & Contraindications

Naproxen should be used with caution in patients with cardiac, hepatic and renal impairment, coagulation defect, and previous history of gastro-intestinal ulceration. The drug is contraindicated in patients with a history of hypersensitivity to aspirin or any other NSAID - which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID.

Naproxen suppository is contraindicated in children under 12 years of age. The suppository is contraindicated also in patients with any inflammatory lesions of rectum or anus and in patients with recent history of rectal or anal bleeding.

Side-effects

Gastro-intestinal discomfort — nausea, diarrhoea and occasionally bleeding and ulceration.

Hypersensitivity reactions — notably with bronchospasm, rashes and angioedema.

CNS side effect — drowsiness, headache, fluid retention, vertigo, hearing disturbances such as tinnitus, photosensitivity.

A few instances of jaundice, impairment of renal function, thrombocytopenia, and agranulocytosis have been reported.

Drug Interaction :

Use in patients receiving ACE inhibitors may potentiate renal diseases. Drug which are Albumin-bound may be displaced from their binding sites as a result of the naproxen anions' affinity for protein. Use with caution when given concomitantly with coumarin-type anticoagulants, hydantion sulfonamides, or sulfonylureas. Concomitant administration is not recommended because reduction in the antihypertensive effect of propranolol and other beta-blockers may occur. Concurrent administration of probenecid or methotrexate should be done cautiously to prevent potential naproxen and methotrexate toxicity, respectively.

Pregnancy & Lactation

There are no well controlled studies in pregnant women. The drug should not be used during pregnancy unless clearly needed. Because of the possible adverse effects of prostaglandin inhibiting drugs on neonates, use in nursing mothers must be avoided.

Storage**Tablet:**

Protect from light and store below 30⁰ C temperature in a dry place.

Suppository:

Store below 25⁰C temperature.

Gel:

Store in a cool and dry place protected from light.

How Supplied

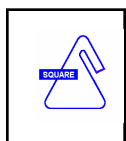
Sonap[®] 250 tablet: Box containing 5x10's tablets in blister pack.

Sonap[®] 500 tablet: Box containing 5 x 6's tablets in blister pack.

Sonap[®] 500 Suppository: Box containing 2x5 suppositories in blister/strip packs.

Sonap[®] Gel: Tube containing 15 gm gel.

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Manufactured by

Square
Pharmaceuticals Ltd.
Bangladesh