NAPROBEST®

Naproxen Sodium

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1. Product Name

NAPROBEST® 250 Tablet

NAPROBEST® 500 Tablet

2. Name and Strength of Active Ingredient(s)

NAPROBEST® 250 mg: Each tablet contains Naproxen Sodium USP equivalent to Naproxen 250mg.

NAPROBEST® 500 mg: Each tablet contains Naproxen Sodium USP equivalent to Naproxen 500mg.

3. Product Description

NAPROBEST® is Naproxen Sodium, sodium salt form of naproxen, a member of the arylacetic acid group of non-steroidal anti-inflammatory drugs (NSAIDs) with anti-inflammatory, analgesic and antipyretic properties. Both the acid and its sodium salt are used in the treatment of rheumatoid arthritis and other rheumatic or musculoskeletal disorders, dysmenorrhea, and acute gout.

4. Pharmacodynamics & Pharmacokinetics

Pharmacodynamics:

Naproxen has analgesic and antipyretic properties. The mechanism of action of Naproxen, like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2).Naproxen is a potent inhibitor of prostaglandin synthesis in vitro. Naproxen concentrations reached during therapy have produced in vivo effects. Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin in inducing pain in animal models. Prostaglandins are mediators of inflammation. Because Naproxen is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

Pharmacokinetics:

Although Naproxen itself is well absorbed, the sodium salt form is more rapidly absorbed, resulting in higher peak plasma levels for a given dose.

Absorption:

Naproxen sodium is freely soluble in water and is completely absorbed from the gastrointestinal tract. Plasma levels are obtained in patients within 20 minutes and peak levels in approximately 1 hour. It is extensively bound to plasma protein and has a plasma half-life of approximately 13 hours.

Distribution:

The volume of distribution of Naproxen is small, about 0.1 l/kg. Steady-state concentrations are obtained in two days, and no significant accumulation has been observed. More than 99% of the circulating Naproxen is albumin-bound.

Metabolism:

Naproxen is either metabolised (cytochromeP450) to 6-0-desmethyl naproxen (6-DMN) and conjugated to glucuronides or left un-metabolised. Naproxen does not induce metabolizing enzymes.

Excretion:

Naproxen and its metabolites are primarily excreted via the kidneys (>95%). The elimination half-life of naproxen is about 14 hours. The rate of excretion has been found to coincide closely with the rate of drug disappearance from plasma.

5. Indications:

Naproxen Sodium is clinically proven for rheumatoid arthritis (RA),osteoarthritis (OA),Ankylosing spondylitis (AS),tendinitis, bursitis, acute gout, primary dysmenorrhea (PD),the relief of mild to moderate pain.

6. Recommended Dose and Administration

Pain:

500 mg PO initially, then 250 mg PO every 6-8hr or 500 mg PO every12hr PRN(as needed); not to exceed 1250 mg/day Naproxen base on day 1; subsequent daily doses should not exceed 1000 mg Naproxen base. Extended release: 750-1000 mg PO every day; may temporarily increase to 1500 mg/day if tolerated well and clinically indicated.

Rheumatoid Arthritis, Osteoarthritis, Ankylosing Spondylitis :

500-1000 mg/day PO divided every12hr; may increase to 1500 mg/day if tolerated well for limited time Extended release: 750-1000 mg PO every day; may temporarily increase to 1500 mg/day if tolerated well and clinically indicated.

Dysmenorrhea:

500 mg PO initially, then 250 mg PO every 6-8hr or 500 mg PO q12hr (long-acting formula); not to exceed 1250 mg/day on first day; subsequent doses should not exceed 1000 mg/day Naproxen base.

Gout, Acute :

750 mg PO initially, followed by 250 mg every8hr until attack subsides. Extended release: 1000-1500 mg every day, followed by 1000 mg every day until attack subsides.

7. Contraindication

Naproxen Sodium is contraindicated in patients.

- Who have previously exhibited hypersensitivity to Naproxen Sodium.
- With a history of asthma, urticaria, or allergic-type reactions after taking acetylsalicylic acid (ASA) or other NSAIDs (rhinosinusitis, urticaria/angioedema, nasal polyps, asthma). Fatal anaphylactoid reactions have occurred in such individuals. Individuals with the above medical problems are at risk of a severe reaction even if they have taken NSAIDs in the past without any adverse reaction.
- With active peptic ulcers, a history of recurrent ulceration,or active gastrointestinal bleeding.
- With inflammatory bowel disease,severe liver impairment or active liver disease.
- With severe renal impairment (creatinine clearance <30 mL/min or 0.5 mL/sec).
- In women in their third trimester of pregnancy because of risk of premature closure of the ductus arteriosus and prolonged parturition.

8. Warnings and Precautions

General:

Patients who are taking any other analgesic or anti-inflammatory drugs (including Naproxen or Naproxen Sodium), steroids, diuretics or drugs that influence hemostasis.

Cardiovascular :

Patients with severe cardiac impairment and a history of hypertension. Naproxen may attenuate acetylsalicylic acid's antiplatelet effect. Patients should talk to their doctor if they are on an acetylsalicylic acid regimen.

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Gastrointestinal:

A patient with a medical history of gastrointestinal disease including peptic ulceration.

Hematologic:

Patients with coagulation disturbances. Numerous studies have shown that concomitant use of NSAIDs and anti-coagulants increases the risk of bleeding

Neurologic:

Some patients may experience drowsiness, dizziness, blurred vision vertigo, tinnitus, hearing loss, insomnia or depression with the use of NSAID such as NAPROBEST®.

Skin:

Patients with a medical history of urticaria and angioedema.

Fertility:

May impair fertility and is not recommended in women attempting to conceive .In women who have difficulty conceiving withdrawal of Naproxen should be considered.

9. Special Populations:

Geriatrics:

Patients older than 65 years and frail or debilitated patients are more susceptible to a variety of adverse reactions from NSAIDs. The incidence of these adverse reactions increases with dose and duration of treatment. In addition, these patients are less tolerant to ulceration and bleeding. Older patients are also at risk of lower esophageal injury including ulceration and bleeding.

Pregnancy and Lactation:

Pregnancy Category: C

10. Drug-Drug Interactions:

Acetylsalicylic acid (ASA) or other NSAIDs, Albumin Bound Drugs, Antacids Anti-coagulants, Anti-hypertensives, Anti-platelet Agents (includingASA), Cholestyramine, Cyclosporin, Digoxin, Diuretics, Glucocorticoids, Lithium, Methotrexate, Probenecid, Selective Serotonin Reuptake Inhibitors (SSRIs).

11. Undesirable Effects

Gastrointestinal discomfort occurs in more than 30% of patients after oral administration of 6 g/day. The discomfort disappears when the dose is reduced.

12. Storage Condition

Store NAPROBEST® at room temperature, away from light and moisture.

- Keep all medications away from children and pets.
- Do not flush medications down the toilet or pour them into a drain unless instructed to do so.
- Properly discard this product when it is expired or no longer needed.

13. Dosage Forms and packaging available

NAPROBEST® 250mg Tablet: Each box contains 20x 10 tablets in a blister pack.

NAPROBEST® 500mg Tablet: Each box contains 10x 10 tablets in a blister pack.

NIROG
A Primary Care Division of DJPL

Manufactured by:
Deurali-Janta Pharmaceuticals Pvt. Ltd.
Dhapasi, Kathmandu, Nepal
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