Novas®
Naproxen BP

Insert for prescribing information

Composition
Novas® 500 mg Tablet: Each enteric-coated tablet contains Naproxen BP 500 mg.

Pharmacology
Novas® (Naproxen) is a nonsteroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and antipyretic properties.
Naproxen is a propionic acid derivative related to the arylacetic acid class of drugs. It inhibits synthesis of prostaglandins.

Indication
Novas® is indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and juvenile rheumatoid arthritis. Novas® is also indicated for the treatment of tendonitis, bursitis, acute gout, for the management of pain, primary dysmenorrhea, migraine treatment and prophylaxis.

Dosage and Administration
Onset of pain relief can begin within 1 hour in patients taking Novas®. After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.
Novas® Tablet: For oral use.

Dose in Adults

Chronic conditions: Osteoarthritis/Rheumatoid arthritis/Ankylosing spondylitis/chronic pain states in which there is an inflammatory component: The recommended dose of Novas® is 250 mg or 500 mg taken twice daily (morning and evening).

Acute conditions: Analgesia/Dysmenorrhea/Acute musculoskeletal conditions/Acute pain states in which there is an inflammatory component. The recommended starting dose is Novas® 500 mg followed by Naproxen 250 mg every 6-8 hours or as required. The total daily dose should not exceed 1250 mg.

Acute gout: The recommended starting dose is of 750 mg followed by Naproxen 250 mg every 6-8 hours until the attack has subsided. The total daily dose should not exceed 1250 mg.

Migraine: 750 mg at the first symptom of an impending attack. An additional dose of Naproxen 250 mg to 500 mg can be taken throughout the day, if necessary, but not before half an hour after the initial dose. For prophylaxis of migraine headache, the dose of Novas® is 500 mg twice daily. If no improvement is seen within 4-6 weeks, the drug should be discontinued.

Contraindication
Naproxen is contraindicated in patients who have had allergic reactions to Naproxen. It is also contraindicated in patients in whom Aspirin or other nonsteroidal anti-inflammatory/analgesic drugs induce the syndrome of asthma, rhinitis and nasal polyps. Naproxen is contraindicated in patients with active peptic ulceration or active gastrointestinal bleeding. Naproxen is contraindicated in children under 2 years of age since safety in this age group has not been established.

Warning and Precaution
Gastrointestinal ulceration, bleeding and perforation: Gastrointestinal mucosal injury may occur. Serious gastrointestinal toxicity, such as gastrointestinal irritation, bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAIDs including Naproxen therapy. In patients with a history of gastrointestinal disease, Naproxen should be given under close supervision.

Renal effects: There have been reports of impaired renal function, renal failure, acute interstitial nephritis, hematuria, proteinuria, renal papillary necrosis and occasionally nephrotic syndrome associated with Naproxen.

Hematological: Naproxen decreases platelet aggregation and prolongs bleeding time. This effect should be kept in mind when bleeding times are determined.

Hepatic effects: Hepatic abnormalities may be the result of hypersensitivity rather than direct toxicity. Severe hepatic reactions, including jaundice and hepatitis (some cases of hepatitis have been fatal) have been reported with it.

Precautions to elderly patients: Use of the lower end of the dosage range is recommended.

Combination with other NSAIDs: The combination of other NSAIDs is not recommended, because of the cumulative risks of inducing serious NSAID-related adverse events.

Side Effects
Common: Gastrointestinal: abdominal pain, heartburn, constipation, diarrhoea, dyspepsia, heartburn, nausea, stomatitis. Central nervous system: dizziness, drowsiness, headache, lightheadedness, vertigo. Dermatologic: ecchymosis, itching (pruritus), purpura, skin eruptions, sweating. Special senses: hearing disturbances, tinnitus, visual disturbances. Cardiovascular: dyspnea, edema, palpitations. Renal: glomerular nephritis, haematuria, interstitial nephritis, hyperkalaemia.

Rare: Hematologic: agranulocytosis, hemolytic anemia. Central & peripheral nervous system: cognitive dysfunction, convulsions. Dermatological: urticarial. General: angioneurotic edema, hyperglycemia, hypoglycemia. Reproductive: female infertility. General: thirst.

Use in Pregnancy & Lactation
Pregnancy: Pregnancy Category: C
As with other drugs of this type, naproxen produces delay in parturition in animals and also affects the human fetal cardiovascular system (closure of ductus arteriosus). Therefore, Naproxen should not be used during pregnancy unless clearly needed. Labor and delivery: Naproxen is not recommended in labor and delivery because, through its prostaglandin synthesis inhibitory effect, Naproxen may adversely affect fetal circulation and inhibit uterine contractions, thus increasing the risk of uterine hemorrhage.

Lactation: The Naproxen anion has been found in the 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.

Drug-interactions
With Medicine: Concomitant administration of antacid or cholestyramine can delay the absorption of Naproxen, but does not affect its extent. Naproxen is highly bound to plasma albumin; Patients simultaneously receiving the drug and a Hydantoin, Sulphonamide or Sulphonylurea should be observed for adjustment of dose if required. Caution is advised when Methotrexate is administered concurrently, since Naproxen and other prostaglandin synthesis-inhibiting drugs have been reported to reduce the clearance of Methotrexate and thus possibly enhance its toxicity. Naproxen can reduce the anti-hypertensive effect of beta-blockers. Concomitant use of NSAIDs with ACE inhibitors or angiotensin receptor blockers may increase the risk of renal dysfunction, especially in patients with pre-existing poor renal function. Naproxen may inhibit the natriuretic effect of Frusemide. Inhibition of renal Lithium clearance leading to increases in plasma Lithium concentrations has been reported. Naproxen decreases platelet aggregation and prolongs bleeding time. This effect should be kept in mind when bleeding times are determined.

With Food and Others: Concomitant administration of food can delay the absorption of Naproxen, but does not affect its extent. After administration of Naproxen tablets peak plasma levels are attained 2-4 hours, depending on the food intake.

Overdose
Significant overdose of the medicine may be characterised by dizziness, drowsiness, epigastric pain, abdominal discomfort, indigestion, transient alterations in liver function, hypoprothrombinaemia, renal dysfunction, metabolic acidosis, apnoea, disorientation, nausea or vomiting. Gastrointestinal bleeding may occur. Hypertension, acute renal failure, respiratory depression and coma may occur after the ingestion of NSAIDs, and may occur following an overdose.

Patients should be managed by symptomatic and supportive care following NSAIDs overdose. There are no specific antidotes. Prevention of further absorption (e.g. activated charcoal) may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose. Forced diuresis, alkalinisation of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding. Due to the sustained-release characteristic of Naproxen SR tablets, it should be expected that Naproxen will continue to be absorbed for up to 16 hours after ingestion.

Storage
Store at temperature not exceeding 30° C in a dry place. Protect from light.

Commercial Pack
Novas® 500 mg Tablet: Each box contains 3X10's tablets in Alu-Alu blister strips.

For child safety: Keeping medicines out of reach

MAKS
Manufactured for
Maks Drug Limited
Plot No-S 58-59, BSCIC I/A, Konabari,
Joydebpur, Gazipur, Bangladesh.
by NAAFCO Pharma Ltd.
Bandia, Meduary, Bhaluka,
Mymensingh, Bangladesh.