TOREX-IR 550 mg ٹوریکس۔آئی آر

(Naproxen Sodium) ۵۵۰ملی گرام (نیپروکسن سوڈیم)

COMPOSITION

Each film coated tablet contains:

Naproxen Sodium ..... 550 mg

Product Complies U.S.P. Specifications

DESCRIPTION

Torex-IR 550 mg Tablet contains Naproxen Sodium, a non-steroidal anti-inflammatory drug (NSAID).
Naproxen Sodium possesses analgesic and anti-inflammatory properties and is used for the relief of pain and inflammatory conditions.

CLINICAL PHARMACOLOGY

Mechanism of Action

Naproxen is a non-steroidal anti-inflammatory drug with analgesic and anti-inflammatory activity. Its therapeutic effects are associated with inhibition of prostaglandin synthesis, resulting in reduction of pain and inflammation.
Naproxen Sodium is the sodium salt of naproxen and is used for the symptomatic treatment of painful and inflammatory conditions.

THERAPEUTIC INDICATIONS

Torex-IR 550 mg Tablet is indicated for the treatment of:

Mild to moderate pain.
Rheumatoid arthritis.
Osteoarthritis.
Acute attacks of gout.
Ankylosing spondylitis.
Menstrual pain (dysmenorrhoea).
Acute migraine headache pain.
Pain due to bleeding associated with insertion of an intrauterine device (IUD).

DOSAGE AND ADMINISTRATION

The dosage should be individualized according to the patient's condition and response to treatment.
The lowest effective dose should be used for the shortest duration necessary to control symptoms.

Adults and children over 16 years of age
The usual daily dose is 550 mg to 1100 mg of naproxen sodium.
The recommended initial dose is 550 mg, followed, if required, by 275 mg every 6 to 8 hours, depending on the severity of the condition.
The dosage may be modified by the physician according to the clinical response.

Rheumatoid Arthritis, Osteoarthritis and Ankylosing Spondylitis
The recommended dose is:
550 mg twice daily, morning and evening,
or
1100 mg once daily, as directed by the physician.

Acute Gout
The recommended initial dose is 825 mg, followed by 275 mg every 8 hours until the acute attack subsides.

Dysmenorrhoea
The recommended initial dose is 550 mg, followed, if necessary, by 275 mg every 6 to 8 hours.

Migraine Headache
The recommended initial dose is 825 mg when the first symptoms of migraine appear, followed by 275 mg approximately 30 minutes later, if required.

Menorrhagia
The recommended dose on the first day is 825 mg to 1375 mg, divided into two doses, followed by 550 mg to 1100 mg daily, divided into two doses, for a maximum period of four days.

Children and Adolescents under 16 years
Torex-IR 550 mg Tablet is not intended for use in children and adolescents under 16 years of age.

Elderly
The dose should be reduced in elderly patients. The lowest effective dose should be used for the shortest possible duration.

Patients with Renal and/or Hepatic Impairment
In patients with renal and/or hepatic impairment, the dose should be reduced. The lowest effective dose should be used for the shortest possible duration.
Torex-IR should not be used in patients with severe renal or hepatic impairment.

METHOD OF ADMINISTRATION
Torex-IR 550 mg Tablet is intended for oral administration.
The tablet should be swallowed with a sufficient amount of water and is preferably taken with food.
The tablet can be divided into equal doses where applicable.

CONTRAINDICATIONS
Torex-IR 550 mg Tablet is contraindicated in patients with:

Hypersensitivity to naproxen sodium or any component of the product.
A history of bronchial asthma, urticaria or rhinitis precipitated by acetylsalicylic acid or other NSAIDs.
Active or recurrent peptic ulcer or gastrointestinal bleeding.
A history of gastrointestinal bleeding or perforation associated with previous NSAID treatment.
Severe heart failure.
Severe hepatic impairment.
Severe renal impairment.
Ulcerative colitis.
Third trimester of pregnancy.
Concomitant use of other NSAIDs.

PRECAUTIONS AND WARNINGS
Gastrointestinal Effects
Naproxen may cause gastrointestinal irritation, ulceration, bleeding or perforation. These events may occur with or without previous warning symptoms and may, in some cases, be fatal.
The risk is increased with higher doses, prolonged treatment, a previous history of peptic ulcer or gastrointestinal bleeding, and in elderly patients.
Patients should be instructed to discontinue treatment and seek medical attention if severe or persistent abdominal pain or black stools occur.

Elderly Patients
Elderly patients are at increased risk of gastrointestinal adverse effects and other complications associated with NSAID therapy. The lowest effective dose should be used for the shortest possible duration.

Gastrointestinal Disorders
Naproxen should be used with caution in patients with a history of gastrointestinal disorders.
Patients with Crohn's disease or ulcerative colitis should be closely monitored, as NSAIDs may exacerbate these conditions.

Asthma and Allergic Disorders
Naproxen should be used with caution in patients with asthma or allergic disorders, including rhinitis and nasal polyps, as bronchospasm may occur.

Renal, Hepatic and Cardiac Disorders
Naproxen should be used with caution in patients with renal, hepatic or cardiac impairment.
NSAIDs may cause fluid retention and oedema, particularly in patients with heart failure or hypertension.

Cardiovascular Effects
Naproxen and other NSAIDs may be associated with a small increased risk of myocardial infarction or stroke. The risk may increase with higher doses and prolonged treatment.
Patients with cardiovascular disease, a history of stroke, hypertension, diabetes, hypercholesterolaemia or other cardiovascular risk factors should be evaluated before treatment.
The recommended dose and duration of treatment should not be exceeded.

Effects on Infection
Naproxen may mask the usual signs and symptoms of infection, including fever and pain. Appropriate clinical evaluation should therefore be considered in patients with suspected infection.

Blood Coagulation
Caution is required in patients receiving medicines that affect blood coagulation or increase the risk of gastrointestinal ulceration and bleeding.
These include oral anticoagulants, antiplatelet agents, corticosteroids and selective serotonin reuptake inhibitors (SSRIs).

Visual Disturbances
Patients who develop visual disturbances during treatment should undergo appropriate ophthalmological evaluation.

Fertility
Naproxen may impair female fertility. Women who are planning to become pregnant or who have difficulty becoming pregnant should inform their physician.

DRUG INTERACTIONS
Naproxen may interact with several medicines and may alter their effects.
Tell your doctor if you are receiving any of the following:

- Antacids or cholestyramine, which may affect the absorption of naproxen.
- Warfarin and other anticoagulants, due to increased risk of bleeding.
- Aspirin or other antiplatelet agents, due to increased gastrointestinal and bleeding risks.

- Sulphonylureas, used in the treatment of diabetes.
- Hydantoin derivatives, used in the treatment of epilepsy.
- Angiotensin receptor blockers and diuretics, used in the treatment of hypertension.
- Furosemide, due to possible reduction in its diuretic effect.
- Lithium, due to possible increase in lithium concentrations.
- Methotrexate, due to possible increased toxicity.
- Corticosteroids, due to increased risk of gastrointestinal ulceration and bleeding.
- Other NSAIDs, including other medicines containing naproxen.

Patients receiving concomitant medicines should be appropriately monitored.

PREGNANCY AND LACTATION

Pregnancy

Naproxen should not be used during pregnancy unless clearly necessary and prescribed by a physician.
Use during the first and second trimesters should be avoided unless the potential benefit outweighs the potential risk. If treatment is considered necessary, the dose and duration should be limited to the minimum required.
Use during the third trimester of pregnancy is contraindicated.

Breast-feeding

Naproxen should not be administered during breast-feeding.

Fertility

Naproxen may reduce female fertility and may make it more difficult to conceive.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Naproxen may cause dizziness, drowsiness, vertigo or visual disturbances.
Patients who experience these effects should exercise caution when driving or operating machinery.

ADVERSE REACTIONS

The most frequently reported adverse effects associated with naproxen involve the gastrointestinal tract.

Gastrointestinal Disorders

Gastritis, dyspepsia, abdominal discomfort, nausea, vomiting, diarrhoea, constipation, flatulence, gastrointestinal bleeding, peptic ulceration, gastrointestinal perforation, stomatitis, oesophagitis and pancreatitis may occur.
Exacerbation of ulcerative colitis and Crohn's disease has also been reported.

Blood and Lymphatic System Disorders
Agranulocytosis, aplastic anaemia, haemolytic anaemia, eosinophilia, leucopenia and thrombocytopenia may occur.

Immune System Disorders
Anaphylactic reactions and angioneurotic oedema have been reported.

Nervous System Disorders
Dizziness, drowsiness, headache, vertigo, cognitive dysfunction, insomnia, sleep disturbances, seizures and aseptic meningitis may occur.

Psychiatric Disorders
Difficulty concentrating, depression and sleep disturbances may occur.

Eye Disorders
Visual disturbances, corneal opacity, optic papillitis, retrobulbar neuritis and papilloedema have been reported.

Ear and Labyrinth Disorders
Hearing disturbances, tinnitus and hearing loss may occur.

Cardiac Disorders
Palpitations, congestive heart failure and hypertension may occur.
NSAIDs including naproxen may be associated with an increased risk of myocardial infarction and stroke.

Vascular Disorders
Vasculitis and oedema may occur.

Respiratory Disorders
Asthma, dyspnoea, eosinophilic pneumonitis and pulmonary oedema have been reported.

Hepatobiliary Disorders
Hepatitis and jaundice may occur. Abnormal liver function tests and, rarely, liver injury have been reported.

Skin and Subcutaneous Tissue Disorders
Pruritus, rash, sweating, hair loss, skin peeling, photosensitivity reactions and other skin reactions may occur.
Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported rarely.

Musculoskeletal and Connective Tissue Disorders
Muscular pain and muscular fatigue may occur.

Renal and Urinary Disorders
Haematuria, interstitial nephritis, nephrotic syndrome, renal impairment and renal papillary necrosis may occur.

Reproductive System and Breast Disorders
Infertility may occur.

General Disorders
Malaise, fever, thirst and sore throat may occur.

Laboratory Investigations
Abnormal liver function tests, increased serum creatinine and hyperkalaemia may occur.
If any adverse effect becomes serious, or if any adverse effect not listed above occurs, the patient should consult a physician or pharmacist.

OVERDOSAGE
In case of overdose, patients should be monitored for signs and symptoms of adverse reactions and appropriate symptomatic treatment should be instituted.

Symptoms of naproxen overdose may include:
Drowsiness.
Heartburn.
Indigestion.
Nausea.
Vomiting.
Seizures in severe cases.

In the event of significant or accidental overdose, appropriate medical management should be initiated.

STORAGE
Store below 30°C, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

PRESENTATION
Torex-IR 550 mg Tablets are available as:
2 × 10's blister pack in a carton.

Manufactured by:
Platinum
Pharmaceuticals (Pvt) Ltd.
A-20, North Western Industrial Zone
Bin Qasim Karachi 75020 Pakistan