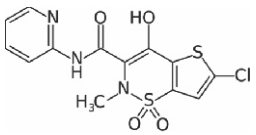
Lornac Tablet
(L o r n o x i c a m) 8mg

لورنیک ٹیبلیٹ
(لورنوکسی کیم) ۸ملی گرام

COMPOSITION
Each film coated tablet contains:
L o r n o x i c a m ..... 8 m g
(Innovator's Specifications)

DESCRIPTION
LORNAC (Lornoxicam) is a nonsteroidal anti-inflammatory drug (NSAID) of the oxicam class with analgesic (pain relieving), anti-inflammatory and antipyretic (fever reducing) properties. It is available in oral and parenteral formulations.
Lornoxicam differs from other oxicam compounds in its potent inhibition of prostaglandin biosynthesis, a property that explains the particularly pronounced efficacy of the drug. Lornoxicam is approved for use in Japan.Molecular formula of Lornoxicam is as follows
C13H10ClN3O4S2Structural formula of Lornoxicam is as follows:



MODE OF ACTION
Lornoxicam is a non-steroidal anti-inflammatory drug with analgesic properties and belongs to the class of oxicams. Lornoxicams mode of action is mainly related to the inhibition of the prostaglandin synthesis (inhibition of the cyclooxygenase enzyme) leading to desensitisation of peripheral nociceptors and consequently inhibition of inflammation. A central effect on nociception, which seems to be independent of anti-inflammatory effects,has also been suggested.

DOSAGE & ADMINISTRATION
Acute pain
8-16 mg Lornoxicam given in doses of 8 mg.An initial dose of 16 mg followed by 8 mg 12 hours later can be given on the first treatment day. After the first treatment day the maximum recommended daily dose is 16 mg.
Additional information on special populations
Children and adolescents
Lornoxicam is not recommended for use in children and adolescents below age 18 because of a lack of data on safety and efficacy.
Elderly
No special dosage modification is required for elderly patients above age 65 unless renal or hepatic function is impaired. Lornoxicam should be administered with precaution as gastrointestinal adverse effects are less well tolerated in this group.
Renal impairment
Reduction of dose frequency of Lornoxicam Rapid to once daily in patients suffering from renal impairment is recommended.
Hepatic impairment
Reduction of dose frequency of Lornoxicam rapid to once daily in patients suffering from hepatic impairment is recommended.

INDICATIONS
Lornoxicam is used for the treatment of various types of pain, especially resulting from inflammatory diseases of the joints, osteoarthritis, surgery, sciatica, and other inflammations.

PHARMACOKINETICS
Absorption
Lornoxicam is absorbed rapidly and almost completely from the gastrointestinal tract. Maximum plasma concentrations are achieved after approximately 30 minutes. The Cmax for lornoxicam Rapid film-coated tablets is higher than Cmax for lornoxicam film-coated tablets and equivalent to Cmax for the parenteral formulation of lornoxicam. The absolute bioavailability of lornoxicam Rapid film-coated tablets is 90-100%. No first-pass effect has been observed. The mean elimination half-life is 3-4 hours. Based on data for lornoxicam film-coated tablets a reduction of Cmax, an increase in Tmax, and a reduction in the absorption (AUC) of lornoxicam may be expected.
Distribution
Lornoxicam is found in the plasma in unchanged form and as its hydroxylated metabolite. The plasma protein binding of lornoxicam is 99% and not concentration dependent.
Biotransformation
Lornoxicam is extensively metabolised in the liver, primarily to the inactive 5–hydroxylornoxicam by hydroxylation. CYP2C9 is involved in this biotransformation of lornoxicam. Due to genetic polymorphism, slow and extensive metabolisers exist for this enzyme, which could result in markedly, increased plasma levels of lornoxicam in slow metabolisers. The hydroxylated metabolite exhibits no pharmacological activity. Lornoxicam is metabolised completely, and approximately 2/3 is eliminated via the liver and 1/3 via the kidneys as inactive substance.
Elimination
The mean elimination half-life of the parent compound is 3 to 4 hours. After oral administration about 50% is excreted in the faeces and 42% through the kidneys, mainly as 5-hydroxylornoxicam. The elimination half-life of 5-hydroxylornoxicam is about 9 hours after a parenteral single or twice daily dose.
In elderly patients above age 65, the clearance is reduced with 30-40%. Apart from reduced clearance, there is no significant change in the kinetic profile of lornoxicam in elderly patients.
There is no significant change in the kinetic profile of lornoxicam in patients with renal or hepatic failure, except for accumulation in patients with chronic liver disease after 7 days of treatment with daily doses of 12 and 16 mg.

SIDE EFFECTS
Lornoxicam has side effects similar to other NSAIDs, most commonly mild ones like gastrointestinal disorders (nausea and diarrhea) and headache. Severe but seldom side effects include bleeding, bronchospasms and the extremely rare Stevens–Johnson syndrome. Other side effects may include:fever and chills, Skin rash, Increased blood pressure, Increased heartbeat, Dizziness, Ringing or buzzing in the ears, Visual disturbances, Fluid Retention, Photosensitivity, Sleeplessness, Kidney Impairment.
PRECAUTIONS
Use of other painkillers
This medicine should be used with extreme caution if you are taking another painkiller medicine. The risk of adverse effects is significantly higher when large amounts of painkillers are taken.

Pediatric use
This medicine is not recommended for use in children as safety and effectiveness of use is not clinically established.

Geriatric use
This medicine should be used with caution in elderly as the risk of adverse effects are significantly high.

Other medicines
This medicine is known to interact with a large number of medicines, which may include medicines that you are consuming. It is advised that you report all your current medicines to the doctor including any herbs and supplements before beginning treatment with this medicine.

Other diseases
This medicine may worsen the symptoms of certain diseases such as asthma, cardiovascular diseases, gastrointestinal bleeding disorders, etc. It is advised that you report all your medical conditions to the doctor before beginning treatment with this medicine.

Systemic lupus erythematosus
This medicine is not recommended for use in patients suffering from systemic lupus erythematosus due to the increased risk of worsening of the patient's condition.

Infections
This medicine should not be used while a patient is suffering from an infection or an infectious disease.

Pregnancy
Use of this medicine should be avoided if you are pregnant or planning a pregnancy in near future. Use of this medicine during the third trimester of pregnancy should be strictly avoided.

Breast-feeding
Use of this medicine should be avoided by nursing mothers as the risk of adverse effects on the infant is high.

DRUG INTERACTIONS
Concomitant administration of lornoxicam and
- Cimetidine: Increased plasma concentrations of lornoxicam. (No interaction between lornoxicam and ranitidine, or lornoxicam and antacids has been demonstrated).
- Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin
Careful monitoring of INR should be undertaken.
- Phenprocoumon: Decreased effect of phenprocoumon treatment.
- Heparin: NSAIDs increase the risk of spinal or epidural hematoma when given concomitantly to heparin in the context of spinal or epidural anesthesia.
-ACE inhibitors: The antihypertensive effect of the ACE inhibitor may decrease.
- Diuretics: Decreased diuretic and antihypertensive effect of loop diuretics, thiazide diuretics and potassium sparing diuretics
- Beta-adrenergic blockers: Decreased antihypertensive efficacy.
- Digoxin: Decreased renal clearance of digoxin.
- Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding
- Quinolone antibiotics: Increased risk of seizures.
- Anti-platelet agents: Increased risk of gastrointestinal bleeding
- Other NSAIDs: Increased risk of gastrointestinal bleeding.
- Methotrexate: Increased serum concentration of methotrexate. Increased toxicity may result. When concomitant therapy has to be used careful monitoring should be undertaken.
- Selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding
- Lithium: NSAIDs inhibit renal clearance of lithium, thus the serum concentration of lithium may increase above toxicity limits. Therefore serum lithium levels require monitoring, especially during initiation, adjustment and withdrawal of treatment.
- Cyclosporine: Increased serum concentration of cyclosporine. Nephrotoxicity of cyclosporine may be enhanced via renal prostaglandin mediated effects. During combined treatment renal function should be monitored.
- Sulphonylureas: Increased risk of hypoglycaemia.
- Known inducers and inhibitors of CYP2C9 isoenzymes: Lornoxicam (as other NSAIDs depending on the cytochrome P450 2C9 (CYP2C9 isoenzyme)) has interactions with known inducers and inhibitors of CYP2C9 isoenzymes
- Tacrolimus: Increase the risk of nephrotoxicity owing to reduced synthesis of prostacyclin in the kidney. During combined treatment renal function should be monitored.
- Pemetrexed: NSAIDs may reduce renal clearance of pemetrexed resulting in increased renal and gastrointestinal toxicity, and myelosuppression.
LORNAC film-coated tablets show a delayed absorption of lornoxicam when given with food. Therefore, LORNAC film-coated tablets should not be taken with food when a quick onset of efficacy (relief of pain) is required. Food may decrease the absorption with about 20% and increase Tmax

CONTRAINDICATIONS
- The drug is contraindicated in patients who must not take other NSAIDs, possible reasons including salicylate sensitivity, gastrointestinal bleeding and bleeding disorders, and severe impairment of heart, liver or kidney function(Serum creatinine > - 700 µmol/L).
- Lornoxicam is not recommended during pregnancy and breastfeeding and is contraindicated during the last third of pregnancy.
- Hypersensitivity to lornoxicam, or any of its excipients. Hypersensitivity (symptoms like asthma, rhinitis, angioedema or urticaria) to other non-steroidal anti-inflammatory drugs, including acetylic salicylic acid.
- Gastro-intestinal bleeding, cerebrovascular bleeding or other bleeding disorders
- Active or history of recurrent peptic ulceration/hemorrhage (two or more distinct episodes of proven ulceration or bleeding)
- Severe hepatic impairment
- Severe renal impairment
- Thrombocytopenia
- History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy - severe heart failure.

STORAGE & INSTRUCTIONS
Store between 15-25°C.
Protect from heat, sunlight and moisture. Keep away from the reach of children.
To be sold on prescription of registered medical practitioner only.

HOW SUPPLIED
LORNAC Tablet 8mg
10's Tablets.

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں

ہدایات:
دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.