RIDCAME

[Lornoxicam]

4mg, 8mg Tablets

رِڈکیم

۴ملی گرام، ۸ملی گرام گولیاں

DESCRIPTION:
RIDCAME (Lornoxicam) is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class with analgesic properties.

QUALITATIVE AND QUANTITATIVE COMPOSITION:
RIDCAME (Lornoxicam) is available for oral administration as:

1. RIDCAME Tablet 4mg
Each film coated tablet contains:
Lornoxicam.....4mg
(Product Specs.: Sigma)

2. RIDCAME Tablet 8mg
Each film coated tablet contains:
Lornoxicam.....8mg
(Product Specs.: Sigma)

CLINICAL PHARMACOLOGY:
Mechanism of Action:
The mode of action of lornoxicam is partly based on inhibition of prostaglandin synthesis (inhibition of cyclo-oxygenase enzyme). The inhibition of cyclo-oxygenase does not result in an increase formation of leukotriene. As with other non-steroidal anti-inflammatory drugs the mechanism of the analgesic action of lornoxicam has not been fully determined.
PHARMACOKINETICS:
Absorption:
Lornoxicam is absorbed rapidly and almost completely from the gastrointestinal tract. Maximum plasma concentrations are achieved after approximately 1 to 2 hours. The absolute bioavailability is 90%-100%.
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.
Metabolism:
Lornoxicam is extensively metabolized in the liver, primarily to the inactive 5–hydroxylornoxicam by hydroxylation. CYP2C9 is involved in this biotransformation of lornoxicam. Lornoxicam is metabolized completely, and approximately 2/3 is eliminated via liver and 1/3 via kidneys as inactive substance. The hydroxylated metabolite exhibits no pharmacological activity. Lornoxicam (like Diclofenac and other oxicams) is metabolized by cytochrome P450 2C9. Due to genetic polymorphism slow and rapid metabolisers exist for this enzyme, which could result in markedly increased plasma levels of lornoxicam in slow metabolisers.
Excretion:
The mean elimination half-life is 3 to 4 hours. After oral administration about 50% is excreted in the feces and 42%, through the kidneys, mainly as 5-hydroxylornoxicam.
Special Population:
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 to once daily in patients suffering from renal impairment is recommended.
Hepatic Impairment:
Reduction of dose frequency of lornoxicam to once daily in patients suffering from hepatic impairment is recommended. Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.

INDICATIONS:
RIDCAME (Lornoxicam) Tablets are indicated for:
- Short term treatment of moderate pain, such as pain after dental surgery.
- Short term treatment of mild to moderate pain associated with extra articular inflammation.
- Treatment of pain associated with acute lumbo-sciatica.
- Symptomatic treatment of pain and inflammation in osteoarthritis and rheumatoid arthritis.

DOSAGE AND METHOD OF ADMINISTRATION:
RIDCAME (Lornoxicam) Tablets are supplied for oral administration and should be taken before meals with a sufficient quantity of liquid. For all patients the appropriate dosing regimen should be based upon individual response to treatment.
Dosage for the Treatment of Pain:
A dose of 8mg to 16mg per day is recommended and should be taken in 2 single doses. The daily dose should not exceed 16mg.
Dosage for the Treatment of Rheumatoid Arthritis and Osteoarthritis:
The recommended daily dose is 8mg-16mg preferably given as 8mg twice daily.
Dosage in case of Impaired Kidney or Liver Function:
For patients with renal or hepatic impairment the maximal recommended daily dose is reduced to 8mg.

CONTRAINDICATIONS:
RIDCAME is contraindicated in patients:
- Allergic to lornoxicam or any of the component of product.
- Who have suffered from hypersensitivity reactions (Asthma, rhinitis, angioedema or urticaria) to other non steroidal anti-inflammatory medicines, including acetylsalicylic acid.
- With gastrointestinal bleeding, cerebrospinal bleeding or other bleeding disorders.
- With active peptic ulceration or with a history of recurrent peptic ulceration.
- With severe liver impairment.
- With severe renal impairment (serum creatinine >700µmol/L).
- With severe heart insufficiency.
- With severe thrombocytopenia.
- Who are elderly (>65 years) and weighing less than 50kg and undergoing acute surgery.
- Children (under 18 years).

PRECAUTIONS:
Gastro-intestinal ulceration and bleeding in medical history:
Clinical monitoring at regular intervals is recommended. Patients developing peptic ulceration and/or gastro-intestinal bleeding while taking lornoxicam should discontinue medicine administration with appropriate therapeutic actions being taken.

Renal Impairment:
Patients with mild renal impairment (serum creatinine 150-300µmol/L) should be monitored quarterly, patients with moderate renal impairment (serum creatinine 300- 700µmol/L) should be monitored at 1 to 2 month intervals. Treatment with lornoxicam should be discontinued if renal function deteriorates during treatment.
Patients with coagulation disorders:
Careful clinical monitoring and laboratory assessment is recommended (e.g., PTT).
Liver diseases (e.g. liver cirrhosis):
Clinical monitoring and laboratory assessment at regular intervals is recommended (e.g., liver enzymes).
Long term treatment (longer than 3 months):
A regular laboratory assessment of hematology (hemoglobin), renal function (creatinine) and liver enzymes is recommended.
Patients with hypertension and/or obesity:
The monitoring of blood pressure and renal function is recommended in this population.
Elderly patients (65 years or above):
In patients 65 years of age and above, it is recommended that the renal and hepatic functions are monitored.
Pregnancy:
Lornoxicam is contraindicated during pregnancy.
Lactation:
There are no data on the excretion of lornoxicam in human breast milk. Lornoxicam is excreted in milk of lactating rats in relatively high concentrations. Therefore lornoxicam should not be used in breastfeeding women.

DRUG INTERACTIONS:
Anticoagulants or platelet aggregation inhibitors:
Concomitant administration of lornoxicam with anticoagulants or platelet aggregation inhibitors may prolong the bleeding time.
Sulphonylureas:
Concomitant administration of lornoxicam with sulphonylurea may increase the hypoglycemic effect.
Other non-steroidal anti-inflammatory medicines and aspirin:
Concomitant administration of lornoxicam with other NSAID and aspirin increases the risk of adverse reactions.
Diuretics:
Concomitant administration of lornoxicam with diuretics decreases diuresis and antihypertensive effect of loop diuretics and thiazide diuretics.
ACE inhibitors:
Concomitant administration of lornoxicam with ACE inhibitor may decrease the antihypertensive effect of the ACE inhibitor and there is a risk of acute renal insufficiency.
Lithium:
Concomitant administration of lornoxicam with lithium inhibits renal clearance of lithium, thus causing increased serum concentration of lithium.
Methotrexate:
Concomitant administration of lornoxicam with methotrexate may cause an increase in serum concentration of methotrexate and results in increased toxicity.
Cyclosporine:
Concomitant administration of lornoxicam with cyclosporine may cause an increase in serum concentration of cyclosporine and may result in nephrotoxicity via renal prostaglandin mediated effects.
Cimetidine:
Concomitant administration of lornoxicam with cimetidine results in higher plasma concentrations of lornoxicam.
Digoxin:
Concomitant administration of lornoxicam with digoxin results in decreased renal clearance of digoxin.
Inducers and inhibitors of CYP2C9 Isoenzymes:
Lornoxicam has interactions with known inducers and inhibitors of CYP2C9 isoenzymes such as phenytoin, amiodarone, miconazole, tranylcypromine and rifampicin.

ADVERSE REACTIONS:
Common:
Abdominal pain, diarrhea, dyspepsia, nausea, vomiting, dizziness, headache, increase in blood urea nitrogen and creatinine levels, increase in serum transaminase levels and alkaline phosphatase level.
Uncommon:
Constipation, dysphagia, dry mouth, flatulence, gastritis, gastroesophageal reflux, peptic ulceration and/or gastrointestinal bleeding, stomatitis, hemorrhoidal bleeding, thrombocytopenia, increased bleeding time, anemia, decrease in erythrocytes, hemoglobin, leucocytes, alopecia, dermatitis, pruritus, increased sweating, rash urticaria, purpura, ecchymoses, insomnia, somnolence, malaise, weakness, flushing, aseptic meningitis, edema, hypertension, palpitations, tachycardia, hypotension, drowsiness, dizziness, vertigo, paraesthesia, tremor, taste perversion, dyspnea, bronchospasm, cough, rhinitis, micturation disorder, agitation, depression, liver function abnormalities, myalgia, leg cramps, conjunctivitis, vision disorders, tinnitus, allergic reactions, alteration in appetite and weight changes.

OVERDOSAGE:
An overdose with lornoxicam, the following symptoms can be seen: nausea, vomiting, cerebral symptoms (dizziness, ataxia ascending to coma and cramps). Change of liver and kidney function, may be coagulation disorders.In the case of a real or suspected overdose, the medication should be withdrawn. Due to its short half-life, lornoxicam is rapidly excreted. Lornoxicam is not dialyzable. No specific antidote is known to date. The usual emergency measures, including gastric lavage, should be considered. Administering activated charcoal or cholestyramine, immediately after the intake of lornoxicam can lead to diminished absorption of the preparation. Gastrointestinal disorders can be treated with a prostaglandin analogue or ranitidine.

INSTRUCTIONS:
- Store below 30˚C
- Protect from light & moisture
- Keep out of reach of children

To be sold on prescription of a registered medical practitioner.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: دوا کو ۳۰ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

HOW SUPPLIED:
RIDCAME (Lornoxicam) 4mg Tablets are available in pack of 10's.
RIDCAME (Lornoxicam) 8mg Tablets are available in pack of 10's.

SIGMA PHARMA

Manfactured by:
SIGMA PHARMA International (Pvt.) Ltd.
E-50 North Western Industrial Zone,
Port Qasim Authority, Karachi-Pakistan.
www.sigmapharma.com.pk