SUMMARY OF PRODUCT CHARACTERISTICS
LOCAM-MR (Lornoxicam 8 mg / Thiocolchicoside 8 mg Film-Coated Tablets)

1. NAME OF THE MEDICINAL PRODUCT

LOCAM-MR (Lornoxicam 8 mg / Thiocolchicoside 8 mg Film-Coated Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains lornoxicam 8 mg and thiocolchicoside 8 mg.

Excipients with known effect:

Contains quinoline yellow (E104) and lactose. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Yellow, film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAM-MR is indicated for the treatment of: inflammatory diseases of the joints (osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, sciatica, musculoskeletal inflammatory conditions); adjuvant treatment in painful spasm associated with degenerative vertebral disorders, dorsal pain, low back pain, torticollis, traumatological and neurological disorders; and pain after dental surgery.

4.2 Posology and method of administration

One tablet once daily or as directed by the physician. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Method of administration

Oral. Swallow whole with a glass of water. May be taken with food to reduce GI irritation.

4.3 Contraindications

- Hypersensitivity to lornoxicam, thiocolchicoside or to any of the excipients listed in section 6.1.
- Peptic ulceration or active GI bleeding.
- Severe renal impairment.
- History of asthma, urticaria or allergic-type reactions induced by aspirin or other NSAIDs.
- Pregnancy and lactation.
- Active bleeding disorders or haemorrhagic disorders.

4.4 Special warnings and precautions for use

Lornoxicam (NSAID)

Gastrointestinal: GI bleeding, ulceration or perforation can be fatal. Risk is higher with increasing doses, history of ulcer and in the elderly. Use protective agents if at high risk. Cardiovascular: Long-term NSAID use may be associated with an increased risk of arterial thrombotic events. Renal: NSAIDs can precipitate renal impairment; monitor renal function in at-risk patients. Haematological: NSAIDs may affect haemostasis; use with caution in patients with bleeding disorders or on anticoagulant therapy. Reduce dose in patients with diarrhoea. Limit alcohol consumption.

Thiocolchicoside (muscle relaxant)

Photosensitivity reactions have been reported with thiocolchicoside. Advise patients to avoid excessive sunlight exposure during treatment. Thiocolchicoside is metabolised to a colchicine-like metabolite with genotoxic potential in vitro; treatment should not exceed the recommended dose or duration.

Lactose and quinoline yellow

Contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. Contains quinoline yellow (E104), an azo dye that may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulants: NSAIDs may enhance the effect of anticoagulants; monitor. ACE inhibitors and antihypertensives: NSAIDs may reduce antihypertensive effects; combination may increase the risk of renal impairment in the elderly. Ciclosporin: May increase nephrotoxicity. Digoxin: NSAIDs may increase plasma digoxin levels. Diuretics: NSAIDs may reduce diuretic efficacy and increase the risk of renal failure. Sulfonylureas: Possibility of hypoglycaemic effects. Lithium: NSAIDs may increase lithium plasma concentrations. SSRIs: Increased risk of GI bleeding. Quinolone antibiotics: Increased risk of convulsions.

4.6 Fertility, pregnancy and lactation

LOCAM-MR is contraindicated during pregnancy and lactation (see section 4.3). Thiocolchicoside has shown teratogenic potential in animal studies. NSAIDs including lornoxicam inhibit prostaglandin synthesis, which may adversely affect pregnancy. Lornoxicam may impair female fertility.

4.7 Effects on ability to drive and use machines

Lornoxicam may cause dizziness or other CNS effects that could impair the ability to drive and use machines.

4.8 Undesirable effects

Lornoxicam (NSAID class effects): GI disorders (nausea, vomiting, dyspepsia, abdominal pain, diarrhoea, constipation, GI ulceration, GI bleeding); CNS effects (dizziness, headache, somnolence); rash, pruritus; elevated liver enzymes; fluid retention, oedema; renal impairment; hypersensitivity reactions. Thiocolchicoside: Diarrhoea, nausea, abdominal pain (related to colchicine-like metabolite effect); photosensitivity reactions; drowsiness.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Lornoxicam overdose: Symptoms may include nausea, vomiting, drowsiness, dizziness, abdominal pain, and GI bleeding. Treatment is symptomatic and supportive. Thiocolchicoside overdose: Symptoms may include nausea, vomiting and neuromuscular toxicity. Manage supportively.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids, combined with muscle relaxants. ATC code: M09AX (combination).

Lornoxicam: An oxicam NSAID that inhibits prostaglandin biosynthesis by blocking COX-1 and COX-2 in approximately the same concentration range, providing anti-inflammatory, analgesic and antipyretic properties. Thiocolchicoside: A muscle relaxant with GABAergic and glycinergic activity that produces muscle relaxation by binding to GABA-A and glycine receptors in the spinal cord. It reduces muscle spasm and associated pain.

5.2 Pharmacokinetic properties

Lornoxicam: Rapidly and completely absorbed after oral administration. Bioavailability approximately 90–100%. Plasma protein binding >99%. Extensively metabolised in the liver (CYP2C9). Terminal half-life 3–5 hours. Excreted via bile (approximately 50%) and urine (approximately 50%) as inactive metabolites. Thiocolchicoside: Rapidly hydrolysed to its active metabolite (M1), SL-59.0955. Thiocolchicoside itself is poorly absorbed (first-pass effect). Peak plasma concentration of M1 reached within 1 hour. Half-life of M1 approximately 5 hours. Excreted mainly in urine.

5.3 Preclinical safety data

Lornoxicam: Non-clinical data reveal no special hazard for humans. Thiocolchicoside: The metabolite M1 has shown genotoxic potential in vitro; this effect was not confirmed in vivo at therapeutic exposure levels. Reproductive toxicity studies with thiocolchicoside showed teratogenicity in rabbits, and fertility impairment and neonatal toxicity in rats at high doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose BP, mannitol BP, methyl hydroxybenzoate (E218) BP, propyl hydroxybenzoate (E216) BP, povidone K-30 BP, isopropyl alcohol BP (manufacturing solvent), sodium starch glycolate BP, purified talc BP, colloidal anhydrous silica BP, sodium stearyl fumarate BP, hypromellose (E-15) BP, macrogol-6000 BP, quinoline yellow (E104; excipient with known effect) IH, titanium dioxide (E171) BP, dichloromethane BP (manufacturing solvent), hydrogenated castor oil BP.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a cool and dry place below 30°C. Keep out of the reach and sight of children.

6.5 Nature and contents of container

10 tablets per blister; 3 such blisters packed in a carton with package leaflet. Pack size: 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

VITACURA PHARMACEUTICALS

Porur, Chennai – 600116, India.

(Manufactured by: Fredun Pharmaceuticals Ltd., 14, 15, 16,

Zorabian Industrial Complex, Vevoor, Palghar – 401404, India.)

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2018/6266/369ER

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

21.04.2026

10. DATE OF REVISION OF THE TEXT

21.04.2026