

Patient Information Leaflet

Please read this leaflet carefully before you start to take your medicine.
This leaflet gives you important information about this medicine.

R_x ACECLOFENAC, PARACETAMOL & CHLORZOXAZONE TABLETS

Galaxy's
LysodolTM-MR
TABLETS

14630R1

COMPOSITION:

Each film coated tablet contains :

Aceclofenac BP	100 mg
Paracetamol BP	500 mg
Chlorzoxazone USP	250 mg
Excipients	q.s.

DESCRIPTION:

Galaxy's Lysodol-MR tablet is a fixed dose combination of Aceclofenac, Paracetamol and Chlorzoxazone.

Chlorzoxazone is a centrally acting skeletal muscle relaxant. Aceclofenac is Non-Steroidal Anti-Inflammatory drug (NSAID's). It has excellent analgesic and anti-inflammatory properties. Aceclofenac together with Paracetamol provides symptomatic relief in a variety of painful conditions.

PHARMACODYNAMICS:

CHLORZOXAZONE: It is a centrally acting skeletal muscle relaxant for painful musculoskeletal conditions. It inhibits muscle spasm by exerting an effect primarily at the level of the spinal cord and subcortical areas of the brain.

ACECLOFENAC: It is highly effective anti-inflammatory and pain relieving agent with good gastrointestinal safety compared to other NSAIDs. Aceclofenac works by blocking action of enzyme cyclooxygenase which is involved in the production of prostaglandins.

PARACETAMOL: It is an effective anti-pyretic, analgesic with mild anti-inflammatory action.

PHARMACOKINETICS:

CHLORZOXAZONE:

Absorption: After oral administration, Chlorzoxazone is completely absorbed. Peak plasma concentrations are achieved after 1 to 2 hours of administration.

Metabolism: Chlorzoxazone is rapidly metabolized in the liver via cytochrome P450 isoenzyme. The elimination half-life is about 1 hour.

Excretion: It is excreted in the urine primarily as the glucuronide metabolite.

ACECLOFENAC:

Absorption: It is rapidly absorbed and completely absorbed after oral administration. Peak plasma concentrations are reached approximately in 1-3 hours following ingestion.

Distribution: Aceclofenac is highly protein-bound (> 99.7%). The volume of distribution (Vd) is approximately 30L.

Metabolism: Aceclofenac is probably metabolized via CYP2C9 to the main metabolite 4-hydroxyaceclofenac. The mean plasma elimination half-life is 4-4.3 hours.

Excretion: Approximately two-thirds of the administered dose is excreted via the urine, mainly as conjugated hydroxyl metabolites.

PARACETAMOL:

Absorption: Paracetamol is rapidly and completely absorbed after oral administration. Peak plasma concentration occurs after 15 min and 2h of ingestion. Oral bioavailability is about 80% and is independent of dose range.

Distribution: Paracetamol is not bound to plasma proteins (<20%). It distributes rapidly and evenly in most tissues and fluids and has volume of distribution of approx. 0.9L/kg.

Metabolism: Paracetamol is extensively metabolized in the liver.

Excretion: 2-5% of therapeutic dose of is excreted unchanged in urine.

INDICATIONS:

In treatment of severe skeletal spasm and pain associated with such medical orthopedic problems such as sprains, strains, low back pain, myalgias, torticollis, cervical root and disc syndromes.

RECOMMENDED DOSAGE:

As directed by Physician.

Use in children under the age of 15 years is generally not recommended.

Take the medicine with a full glass of water.

MODE OF ADMINISTRATION:

Tablets for oral administration.

WARNING & PRECAUTIONS:

Galaxy's Lysodol-MR tablets should be given with care to elderly patients with renal, hepatic or cardiovascular impairment and those receiving other medications. The lowest effective dose should be used and renal function to be monitored regularly. Chlorzoxazone may cause drowsiness & patients should avoid driving motor vehicle or operate machinery while taking the medicines.

CONTRAINDICATIONS:

- ▶ In patients who have previously shown hypersensitivity reactions (asthma, rhinitis, angioedema and urticaria) to Ibuprofen, aspirin or other NSAID therapy.
- ▶ In patients with active peptic ulcer.
- ▶ In patients with severe hepatic impairment or cardiac or renal impairment.

INTERACTION WITH OTHER MEDICATIONS:

Interaction may occur with digoxin, oral anti-diabetic agents, anti-coagulants, diuretic and other analgesics.

The risk of gastrointestinal bleeding and ulceration associated with NSAIDs is increased when used with corticosteroids, the SSRIs, the SNRI venlafaxine, the antiplatelets clopidogrel and ticlopidine, iloprost, erlotinib, or, possibly, alcohol, bisphosphonates, or pentoxifylline.

Risk of Paracetamol toxicity may increase with concomitant use of other potential hepatotoxic drugs or drugs that induce liver microsomal enzymes.

PREGNANCY & LACTATION:

Galaxy's Lysodol-MR tablets are not recommended in Pregnant and breast feeding women.

UNDESIRABLE EFFECTS:

Galaxy's Lysodol-MR tablets when taken within the recommended dose and duration of treatment has low incidence of side effects. Common gastrointestinal side effects (nausea, diarrhea, abdominal pain) which are mild and reversible may occur. Other side effects like angioedema, bronchospasm headache, vertigo, dizziness, drowsiness, fever and rashes may occur occasionally.

CAUTION:

Overdose of Paracetamol may be injurious to liver.

OVERDOSAGE & TREATMENT:

Do not exceed the recommended intake. In case of overdosage, seek medical advice immediately.

STORAGE:

Store below 30°C, at a dry place.

Protect from light.

Keep medicines out of reach of children.



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