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

℞ ACECLOFENAC & PARACETAMOL TABLETS

14629R1

Galaxy's

Lysodol-P™

TABLETS

COMPOSITION:
Each film coated tablet contains:

Aceclofenac B.P.	100 mg
Paracetamol B.P.	500 mg
Excipients	q.s.

DESCRIPTION:
Galaxy's Lysodol-P tablet is a fixed dose combination of Aceclofenac and Paracetamol. 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:
ACECLOFENAC: It is a novel NSAID known to exhibit multifactor mechanism of action. It is a highly effective anti-inflammatory and pain relieving agent with good gastrointestinal tolerability compared to other NSAIDs. Aceclofenac works by blocking action of enzyme cyclooxygenase which is involved in the production of prostaglandin.

PARACETAMOL: It is an effective anti-pyretic, analgesic with mild anti-inflammatory action.
The combination of Aceclofenac and Paracetamol has a synergistic effect, i.e., they work together to improve overall effect.

PHARMACOKINETICS:
ACECLOFENAC:
Absorption: After oral administration, aceclofenac is rapidly and completely absorbed. Peak plasma concentrations are reached approximately 1-3 hours following ingestion.
Distribution: Aceclofenac is highly protein-bound (> 99.7%). Aceclofenac penetrates into the synovial fluid where the concentrations reach approximately 60% of those in plasma. The volume of distribution is approximately 30L.
Metabolism: 4-hydroxyaceclofenac is the main metabolite of Aceclofenac. 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 hydroxymetabolites. Only 1% of an oral single dose is excreted unchanged.

PARACETAMOL:
Absorption: Paracetamol is rapidly and completely absorbed after oral administration. Peak plasma concentration occurs after 15min 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 Paracetamol is excreted unchanged in urine.

INDICATIONS:
- Management of acute and chronic painful inflammatory conditions such as Osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis.
- Also useful in treatment of painful processes of various etiologies such as odontalgia, myalgia, lower-back pain, lumbago-sciatica, scapula-humeral periarthritis and post-episiotomy pain.

RECOMMENDED DOSAGE:
As directed by Physician.
Use in children under the age of 15 years is generally not recommended.

MODE OF ADMINISTRATION:
Tablets for oral administration.

WARNING & PRECAUTIONS:
Galaxy's Lysodol-P tablets should be given with care to patients with kidney or liver disease including patients taking other drugs that affect the liver. The lowest effective dose should be used and renal function to be monitored regularly.

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 anti-platelets 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-P tablets are not recommended in Pregnant and breast feeding women.

UNDESIRABLE EFFECTS:
Galaxy's Lysodol-P 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.

MEYER

Made in India by : Tirupati Medicare Ltd.
Nahan Road, Paonta Sahib, Dist. Sirmour (H.P.)

Exported by : **MEYER ORGANICS PVT. LTD.**
A-177, Wagle Estate, Thane-400 604 (Mumbai) INDIA.

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