INSERT:

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 TABLETS

Galaxy's

Lysodol™ 100/200 SR

TABLETS

14627R1

COMPOSITION :

GALAXY'S LYSODOL 100 TABLETS		**GALAXY'S LYSODOL 200 SR TABLETS**	
Each film coated tablet contains :		Each film coated sustained release tablet contains :	
Aceclofenac B.P.	100 mg	Aceclofenac B.P.	200 mg
Excipients	q.s.	Excipients	q.s.

DESCRIPTION :
Aceclofenac is an orally administered phenylacetic acid derivative with effects on a variety of inflammatory mediators. It is from the class of Non-Steroidal Anti-Inflammatory drugs (NSAIDs). Through its analgesic and anti-inflammatory properties, aceclofenac provides symptomatic relief in a variety of painful conditions.

PHARMACODYNAMICS :
Aceclofenac 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 is a potent inhibitor of the enzyme cyclooxygenase, which is involved in the production of prostaglandins.

PHARMACOKINETICS :
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.

INDICATIONS :
In the management of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis.

DOSAGE & ADMINISTRATION :
As directed by the Physician.
Tablets for oral administration.

CONTRAINDICATIONS :
- Individuals having hypersensitive to aceclofenac and any of its excipients.
- Patients with a history of aspirin or NSAID related allergic or anaphylactic reactions

or with peptic ulcers or GI bleeding, moderate or severe renal impairment, precipitate attacks of asthma, bronchospasm, acute rhinitis or urticaria or patients who are hypersensitive to these drugs.

- Severe heart failure or severely impaired hepatic or renal organ function and during the last three months of pregnancy.

UNDESIRABLE EFFECTS :

Generally the majority of side effects are reversible and of a minor nature and include gastro-intestinal disorders (dyspepsia, abdominal pain, nausea), rash, ruber, urticaria, symptoms of enuresis, headache, dizziness, and drowsiness.

PRECAUTIONS :

- It should be given with caution to elderly patients with renal, hepatic or cardiovascular impairment and to those receiving other medication. The lowest effective dose should be used and renal function monitored regularly.
- As with other NSAIDs, allergic reactions, including anaphylactic / anaphylactoid reactions, can also occur without earlier exposure to the drug.
- Caution should be exercised in patients with history of coagulation defects and history of liver dysfunction.

PREGNANCY & LACTATION :

The drug in not recommended in pregnant & breast feeding women.

OVERDOSE :

There have been no reports on overdose until now. Management of acute poisoning with NSAIDs essentially consists of supportive and symptomatic measures. Standard supportive measures should be adopted as required.

DRUG INTERACTIONS :

Drug interactions associated with aceclofenac are similar to those observed with other NSAIDs. Aceclofenac may increase plasma concentrations of lithium, digoxin and methotrexate, increase the activity of anticoagulants, inhibit the activity of diuretics, enhance cyclosporin nephrotoxicity and precipitate convulsions when co-administered with quinolone antibiotics.

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.**
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