

## **1.6 PRODUCT INFORMATION**

### **1.6.1 Summary Product Characteristics (SPC)**

#### **1. Name of the Medicinal product**

##### **1.1 Product Name**

Galaxy's Lysodol 100 Tablets

##### **1.2 Strength**

Aceclofenac B.P. 100 mg

##### **1.3 Pharmaceutical Dosage Form**

Oral Tablets

#### **2. Quality and Quantitative Composition**

##### **2.1 Qualitative Declaration**

Aceclofenac B.P.

##### **2.2 Quantitative Declaration**

Each film coated tablet contains –

Aceclofenac B.P. 100 mg

Excipients                      q.s.

#### **3. Pharmaceutical Form**

Film coated Tablets .Yellow colored round shaped film coated tablets, plain on both sides.

#### **4. Clinical particulars**

##### **4.1 Therapeutic Indications**

In the management of osteoarthritis, rheumatoid arthritis, and ankylosing Spondylitis.

##### **4.2 Posology and method of administration**

Galaxy's Lysodol 100 tablets are supplied for oral administration and should be swallowed whole with a sufficient quantity of liquid. The recommended dose is 200 mg daily, taken as two separate 100 mg doses, one tablet in the morning and one in the evening. Or as directed by physician

### **4.3 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.

### **4.4 Special Warnings and precautions for use**

- 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.
- The use of Aceclofenac with concomitant NSAIDs including cyclooxygenase- 2 selective inhibitors should be avoided.

### **4.5 Interaction with other medicinal products and other forms of 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 cyclosporine nephrotoxicity and precipitate convulsions when co-administered with quinolone antibiotics.

### **4.6 Pregnancy and Lactation**

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

### **4.7 Effects on ability to drive and use machine**

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

### **4.8 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, urticaria, symptoms of enuresis, headache, dizziness, and drowsiness.

## 4.9 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.

## 5. Pharmacological properties

### 5.1 Pharmacodynamics Properties

**Pharmacotherapeutic group:** Musculo-Skeletal System

**ATC code:** M01A B16

Aceclofenac is a non-steroidal agent with marked anti-inflammatory and analgesic properties. The mode of action of Aceclofenac is largely based on the inhibition to prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclooxygenase, which is involved in the production of prostaglandins.

### 5.2 Pharmacokinetic Properties

**Absorption:** After oral administration, Aceclofenac is rapidly absorbed and the bioavailability is almost 100%. Peak plasma concentrations are reached approximately 1.25 to 3 hours following ingestion. T max is delayed with concomitant food intake whereas the degree of absorption is not influenced.

**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:** 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 hydroxymetabolites. Only 1% of an oral single dose is excreted unchanged. A slower rate of elimination of Aceclofenac has been detected in patients with decreased liver function after a single dose of Aceclofenac. In a multiple dose study using 100mg once daily, there was no difference in the pharmacokinetic parameters between subjects with mild to moderate liver cirrhosis and normal subjects. In patients with mild to moderate renal impairment, no clinically significant differences in the pharmacokinetics were observed after a single dose.

### 5.3 Preclinical Safety Data

The ingredients are well established, and well documented in published scientific literature, worldwide.

## **6. Pharmaceutical Particulars**

### **6.1 List of Excipients**

1. Pregelatinised Starch BP
2. Microcrystalline Cellulose BP (200)
3. Maize Starch (Dried)
4. Croscarmellose Sodium BP
5. Colloidal Anhydrous Silica BP
6. Purified Talc BP
7. Magnesium Stearate BP
8. Wincoat WT-01120, Yellow
9. Isopropyl Alcohol BP
10. Methylene Chloride

**6.2 Incompatibilities:** Not applicable.

**6.3 Shelf Life:** 36 months

### **6.4 Special precautions for storage**

Store below 30<sup>0</sup> C, in dry place, Protect from light.

Keep medicines out of reach of children

### **6.5 Nature and contents of container**

Each carton contains 3 blister strips each containing 10 tablets

## **7. Manufacture**

Meyer Organics Pvt Ltd