## 1.6.1 Prescribing information (summary of product characteristics)

**Summary Product Characteristics (SPC)**

1. **Name of the Medicinal product**

**1.1 Product Name**

Galaxy's Lysodol MR Tablets

**1.2 Strength**

Aceclofenac B.P. 100 mg

Paracetamol B.P. 500 mg

Chlorzoxazone USP 250 mg

**1.3 Pharmaceutical Dosage Form**

Oral Tablets

2. **Quality and Quantitative Composition**

**2.1 Qualitative Declaration**

Aceclofenac B.P.

Paracetamol B.P.

Chlorzoxazone U.S.P.

**2.2 Quantitative Declaration**

Each film coated tablet contains –

Aceclofenac B.P. 100 mg

Paracetamol B.P. 500 mg

Chlorzoxazone USP 250 mg

Excipients q.s.

3. **Pharmaceutical Form**

Film coated Tablets. Brown coloured oval shaped film coated tablet with breakline on one side and plain on another side.

## 4. Clinical particulars

### 4.1 Therapeutic Indications

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

### 4.2 Posology and method of administration

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.

### 4.3 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.

### 4.4 Special Warnings and precautions for use

Galaxy's Lysodol-MR 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.

### 4.5 Interaction with other medicinal products and other forms of interactions

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 drugsthat induce liver microsomal enzymes.

### 4.6 Pregnancy and Lactation

The drug in 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**

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.

**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**

**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

**5.2 Pharmacokinetic Properties**

ACECLOFENAC

**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 metabolite4-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.

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.

**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 P450isoenzyme.The elimination half-life is about 1 hour.

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

**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. Microcrystalline Cellulose BP (PH 101)
2. Maize Starch BP
3. Sodium Lauryl Sulphate BP
4. Sodium Methylparaben BP
5. Sodium Propylparaben BP
6. Polyvinylpyrrolidone BP (PVPK-30)
7. Purified Water BP
8. Sodium Starch Glycolate BP
9. Purified Talc BP
10. Magnesium Stearate BP
11. Wincoat WT-1930 Brown
12. Methylene Chloride
13. Isopropyl Alcohol BP

**6.2 Incompatibilities**: Not applicable.

**6.3 Shelf Life:** 36 months

**6.4 Special precautions for storage**

Store below $30^0$ 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. Manufacturer

**Meyer Organics Pvt. Ltd.**

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Thane – 400 604. (Mumbai)