SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1: Name of the Medicinal Product:

Lysodol-P Tablets

2: Qualitative and quantitative composition

Each Film coated tablet contains:
Aceclofenac BP.....100 mg

Paracetamol BP.....500 mg

For the full list of excipients, see section 6.1.

3: Pharmaceutical form

Film coated Tablet.
White colour, elongated, biconvex film coated tablet, scored on one side and plain on other side.

4. Clinical Particulars

4.1 Therapeutic indications:

Aceclofenac with Paracetamol Tablet is indicated for:
-Osteoarthritis
-Rheumatoid arthritis
-Ankylosing spondylitis
-Pain
-Inflammation
-Acute musculoskeletal disorders and soft tissue inflammation such as periarthritis, sprains, strains, tenosynovitis, bursitis, pain in fractures and dislocation.
-Relief of pain and inflammation associated with orthopedic, dental, gynecological and other minor surgical procedures.

4.2 Posology and method of administration:

Aceclofenac with Paracetamol Tablet is supplied for oral administration in adults. There are no clinical data on the use of Aceclofenac in children and therefore it is not recommended for use in children.
The maximum recommended dose of Aceclofenac with Paracetamol Tablet is one tablet twice daily.

4.3 Contraindications:

Aceclofenac with Paracetamol Tablet is contraindicated in the following situations:

Patients sensitive to Aceclofenac, Paracetamol or to any of the excipients of the product Patients in whom aspirin or other NSAIDs, precipitate attacks of bronchospasm, acute rhinitis or urticaria or patients hypersensitive to these drugs.

Patients with active or suspected peptic ulcer or gastrointestinal bleeding or bleeding disorders.

Patients with severe heart failure.

4.4 Special warnings and precautions for use:

Aceclofenac with Paracetamol Tablet may cause dizziness. Driving or operating machinery is to be avoided.

Individuals receiving long-term treatment should be regularly monitored for renal function tests, liver function tests and blood counts. It is to be used with caution in hepatic porphyria, coagulation disorders, history of peptic ulcers, ulcerative colitis, Crohn's disease, SLE, cerebrovascular bleeding, pregnancy and lactation. Caution should be exercised in patients with mild to moderate impairment of cardiac, hepatic or renal function and in elderly patients who are more likely to be suffering from these conditions. Caution is also required in patients on diuretic therapy or otherwise at risk of hypovolemia. As with other NSAIDs and combinations, caution is advised in elderly patients who are more likely to have concomitant renal, hepatic orcardiovascularimpaim1ent or receiving concurrent medication.

Pregnancy: The drug in not recommended in pregnant women.

Lactation: The drug in not recommended in breast-feeding women.

4.5 Interactions with other medicinal products and other forms of interaction.

Drug interactions associated with Aceclofenac are similar to those observed with other NSAIDs. Aceclofenac may increase the plasma concentrations of lithium, digoxin and methotrexate. It may increase the activity of anticoagulants, inhibit the activity of diuretics, enhance cyclosporine nephrotoxicity and precipitate convulsions when co-administered with quinolone antibiotics. Co-administration of Aceclofenac with other NSAIDs and corticosteroids are to be avoided due to increased incidence of side-effects.

The risk of Paracetamol toxicity may be increased in patients receiving

other potentially hepatotoxic drugs or drugs that induce hepatic microsomal enzymes. Co-administration of Paracetamol with rifampicin, isoniazid, chloramphenicol, antiepileptic drugs and antiviral drugs is to be avoided. Metoclopromide may increase the absorption of Paracetamol whereas excretion and plasma concentration may be altered when co-administered with probenecid.
Cholestyramine also reduces the absorption of Paracetamol.

4.6 Fertility, Pregnancy and lactation:

Pregnancy: The drug in not recommended in pregnant women.
Lactation: The drug in not recommended in breast-feeding women.

4.7 Effects on ability to drive and use machines:

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects:

Most of the adverse events are minor and reversible with treatment discontinuation.
Effects on gastrointestinal system: dyspepsia, abdominal pain and rise in hepatic enzymes.

Effects on skin: As with other NSAIDs, severe mucocutaneous skin reactions may also occur.
Other reactions: Other rare side-effects include dizziness, constipation, vomiting, ulcerative stomatitis, rash, demmtitis, headache, fatigue, allergic reactions, anemia, granulocytopenia, thrombocytopenia, neutropenia, oedema, palpitation, leg cramps, flushing, purpura, paraesthesia, tremors, gastrointestinal bleeding, gastrointestinal ulceration, pancreatitis, interstitial nephritis, depression, abnormal dreaming, somnolence, insomnia, vasculitis, hypoglycemia, rise in blood urea, serum creatinine and serum potassium.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacy and Poisons Board- Pharmacovigilance Electronic Reporting System (PvERS); https://pv.pharmacyboardkenya.org .

4.9 Overdose:

Aceclofenac

Symptoms: There are no human data available on the consequences of aceclofenac overdose. Symptoms of overdose include headache, nausea, vomiting, epigastric pain, GI irritation, GI bleeding. Rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, hypotension, respiratory depression, fainting, and occasionally convulsions may occur. In cases of significant poisoning acute renal failure and liver damage are possible.
Treatment: If overdose with aceclofenac occurs, absorption should be prevented as soon as possible by means of gastric lavage and treatment with activated charcoal. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, GI irritation, and respiratory depression. Specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism. Renal and liver function should be closely monitored.

Paracetamol

Symptoms: Ingestion of 5 gram or more of paracetamol may lead to liver damage. Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, hemorrhage, hypoglycaemia, cerebral edema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, hematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.
Treatment: Immediate treatment is essential in the management of paracetamol overdose. Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine (approved antidote) may be used up to 24 hours after ingestion of paracetamol. However, the maximum protective effect is obtained up to 8 hours post ingestion.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Analgesic, Anti-inflammatory, Antipyretic

Aceclofenac

The mode of action of aceclofenac is largely based on the inhibition to prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclooxygenase (COX). COX enzymes are involved in conversion of arachidonic acid into prostaglandin (PGs). Prostaglandins are usually responsible for causing pain, inflammation, and fever. Aceclofenac blocks the enzyme COX and thereby inhibit PGs synthesis, thus, produces analgesic and anti-inflammatory effects.

Paracetamol

Analgesic Effect: The mechanism of analgesic action of paracetamol has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Antipyretic Effect: Paracetamol produces antipyretic effect by acting centrally on the hypothalamic heat-regulation center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic properties:

Aceclofenac

After oral administration, aceclofenac is rapidly and completely absorbed as unchanged drug. Peak plasma concentrations are reached approximately 1.25 to 3.00 hours following ingestion. Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The volume of distribution is approximately 25 liters. The mean plasma elimination half-life is around 4 hours. Aceclofenac is highly protein-bound (>99%). Aceclofenac circulates mainly as unchanged drug. The main metabolite detected in plasma is 4'-hydroxyaceclofenac. Approximately two- thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites. No changes in the pharmacokinetics of aceclofenac have been detected in the elderly.

Paracetamol

Paracetamol is readily absorbed from the GI tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. Paracetamol is metabolized in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

5.3 Preclinical safety data:

Aceclofenac

Aceclofenac was not considered to have any mutagenic activity in three in vitro studies and an in vivo study in the mouse.
Aceclofenac was not found to be carcinogenic in either the mouse or rat.
Animal studies indicate that there was no evidence of teratogenesis in rats although the systemic exposure was low and in rabbits, treatment with aceclofenac (10 mg/kg/day) resulted in a series of morphological changes in some fetuses.

Paracetamol

Preclinical data reveal no special hazard for humans with paracetamol based on conventional studies of single and repeated dose toxicity, genotoxicity and carcinogenicity. Studies for the evaluation of toxicity to reproduction and development are not available.

Section 6. Pharmaceutical Particulars:

6.1 List of excipients

Maize Starch, Sodium Benzoate, Povidone (As PVPK-30), Microcrystalline Cellulose, Sodium lauryl sulphate, Magnesium Stearate, Purified Talc, Sodium Starch Glycolate, Croscarmellose sodium, Polacrilin Potassium (As Kyron-T-314), Purified water, Hypromellose (E-15), Colour: Titanium Dioxide, Polyethylene Glycol (As 6000), Iso Propyl Alcohol & Dichloromethane.

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life:

36 Months

6.4 Special precautions for storage:

Stored at a temperature not exceeding 30ºC, in a cool and dark place, protect from direct sunlight.

6.5 Nature and contents of container:

3 x 10s pack: 10 tablets packed in alu-alu blister and such 3 blisters are packed in single carton along with pack insert.

6.6 Special precautions for disposal:

Not applicable.

7. Marketing Authorisation Holder:

GALAXY PHARMACEUTICAL LTD.
1st Floor, Doctors Park, 3rd
Parkland Avenue, P.O.BOX
39107 - 00623, Nairobi
(Kenya).

8. Marketing Authorisation Number(s):

H2015/CTD2532/086

9. Date of First Authorisation/Renewal of the Authorisation:

14th October, 2015

10. Date of Revision of the Text

27th March, 2026