Summary of Product Characteristics

1. Name of the medicinal product

Aceclofenac Tablets 100 mg (Galaxy's Lysodol-100)

2. Qualitative and quantitative composition

Each Film coated tablet contains:
Aceclofenac BP 100 mg
For full list of excipients, see section 6.1.

3. Pharmaceutical form

Film coated Tablet.
Light yellow colour, round shaped, plain on both sides film coated tablets.

4. Clinical particulars

4.1 Therapeutic indications

Symptomatic treatment of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

4.2 Posology and method of administration

Method of administration
[Aceclofenac] 100 mg coated tablets are supplied for oral administration and should be swallowed with at least ½ a glass of liquid. [Aceclofenac] can be taken with food.

Posology

Adults
The maximum recommended dose is 200 mg daily, taken as two separate 100 mg doses, one tablet in the morning and one in the evening.

Elderly
Generally, no dose reduction is necessary, however, consider the precautions in section 4.4.

Paediatric population
The safety and efficacy in children and adolescents has not been established.

Hepatic insufficiency
The dose of aceclofenac should be reduced in patients with mild to moderate hepatic impairment. The recommended initial dose is 100 mg daily.

Renal insufficiency
There is no evidence that the dose of aceclofenac needs to be modified in patients with mild renal impairment, but caution is advised.
Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.

4.3 Contraindications

Aceclofenac is contraindicated in the following situations:

• Patients with a history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy
• Patients with active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding)
• Patients with active bleedings or bleeding disorders
• Patients with severely impaired hepatic or renal organ function
• Patients with severe heart failure, established congestive heart failure (NYHA- class II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
• Pregnancy: especially in the third trimester of pregnancy, unless there are serious reasons for treatment. In this case the lowest effective dose should be used
• Patients hypersensitive to aceclofenac or to any of the excipients listed in section 6.1, or who had an asthma attack, acute rhinitis or urticaria after use of acetylsalicylic acid or other NSAIDs, or patients who are hypersensitive to any of these substances.
• Patients with a history of kidney transplantation
• Patients suffering from a nephrotic syndrome

4.4 Special warnings and precautions for use
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.
The use of [Aceclofenac] with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Gastrointestinal:
Close medical surveillance is needed in patients with the following conditions as these may be exacerbated:
• Symptoms indicative of gastrointestinal disorders involving either the upper or lower gastrointestinal tract
• A history suggestive of gastrointestinal ulceration, bleeding or perforation.
• Ulcerative colitis
• Crohn's disease
• Haematological abnormalities
GI bleeding, ulceration or perforation, which can be fatal, have been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events.
The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk.
Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.
Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSRIs) or anti-platelet agents such as aspirin.

When GI bleeding or ulceration occurs in patients receiving aceclofenac, the treatment should be withdrawn.
NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as their condition may be exacerbated.

Hypersensitivity and skin reactions:
As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug. Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Aceclofenac should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign
of hypersensitivity.
Exceptionally, varicella can trigger serious cutaneous and soft tissues infections complications. To date, the contributing role of NSAIDs in the worsening of these infections cannot be ruled out. Thus, it is advisable to avoid use of aceclofenac in case of varicella

Renal:
The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. The importance of prostaglandins in maintaining renal blood flow should be taken into account in patients with impaired cardiac or renal function, liver dysfunction, those being treated with diuretics or recovering from major surgery, and the elderly.
Patients with mild to moderate renal impairment should be kept under surveillance, since the use of NSAIDs may result in deterioration of renal function. The lowest effective dose should be used and renal function monitored regularly. Effects on renal function are usually reversible on withdrawal of aceclofenac.

Hepatic:
Close medical surveillance is needed in patients suffering from mild to moderate hepatic function impairment.
Aceclofenac should be discontinued if abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash). Hepatitis may occur without prodromal symptoms.
Use of NSAIDs in patients with hepatic porphyria may trigger an attack.

Cardiovascular and cerebrovascular:
Close monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAIDs therapy.
Patients with congestive heart failure (NYHA-I) and patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking), should only be treated with aceclofenac after careful consideration. As the cardiovascular risks of aceclofenac may increase with dose and duration of exposure, the shortest

duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.
Aceclofenac should also be administered with caution and under close medical surveillance to patients with a history of cerebrovascular bleeding.
Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for aceclofenac.

Haematological:
Aceclofenac may reversibly inhibit platelet aggregation.

Respiratory disorders:
Caution is required if administered to patients suffering from, or with a previous history of, bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients.

Elderly:
The elderly has an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. The gastrointestinal bleeding and/or perforation, are often more serious and may occur without warning symptoms or previous history, at any time during treatment. Furthermore, elderly patients are more likely to be suffering from impaired renal, cardiovascular or hepatic function.

Long term treatment:
All patients who are receiving long-term treatment with NSAIDs should be monitored as a precautionary measure (e.g. renal, hepatic function and blood counts). Aceclofenac should be administered with caution and under close medical surveillance to patients with a history of SLE, porphyria, hematopoietic –or coagulation- disorders The use of [Aceclofenac], as with any drug known to inhibit cyclo-oxygenase / prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive. In
women who have difficulty conceiving or who are undergoing investigation of infertility, withdrawal of [Aceclofenac] should be considered.

4.5 Interaction with other medicinal products and other forms of interaction
No pharmacokinetic interaction studies have been performed, except with warfarin.
Aceclofenac is metabolized through cytochrome P450 2C9 and in vitro data indicate that aceclofenac may be an inhibitor of this enzyme. A risk of pharmacokinetic interaction is therefore possible with phenytoin, cimetidine, tolbutamide, phenylbutazone, amiodarone, miconazol and sulphaphenazole. As with other products within the NSAID-group, there also exists a risk of pharmacokinetic interactions with other drugs eliminated by active renal secretion, such as methotrexate and lithium. Aceclofenac is bound practically completely to plasma albumin and consequently the possibility of displacement interactions with other highly protein bound drugs must be borne in mind.

Due to the lack of pharmacokinetic interaction studies the following is based upon knowledge from other NSAIDs:
The following combinations should be avoided:
Methotrexate (high dose): NSAIDs inhibit the tubular secretion of methotrexate and a slight metabolic interaction may also occur, resulting in decreased clearance of methotrexate.
Therefore, during treatment with high dose methotrexate prescription of NSAID drugs should always be avoided.

Methotrexate: The possible interaction between NSAIDs and methotrexate should be born in mind also when low doses of methotrexate are used, especially in patients with decreased renal function. When combination therapy has to be used, the renal function should be monitored. Caution should be exercised if both an NSAID and methotrexate are administered within a 24-hour period, since the methotrexate levels may increase and result in increased toxicity.

Lithium and digoxin: Several NSAID drugs inhibit the renal clearance of lithium, resulting in increased serum concentrations of both. The combination should be avoided unless frequent monitoring of lithium and digoxin levels can be performed.

Diuretics: Aceclofenac, like other NSAIDs, may inhibit the activity of diuretics. Although it was not shown to affect blood pressure control when co-administered with bendrofluazide, interactions with other diuretics cannot be ruled out. When concomitant administration with potassium sparing diuretics is employed, serum potassium should be monitored.

Antihypertensives: NSAIDs may reduce the effect of antihypertensives. The risk of acute renal insufficiency, which is usually reversible, may be increased in some patients with compromised renal function (e.g. dehydrated patients or elderly patients) when ACE-inhibitors or angiotensin II receptor antagonists are combined with NSAIDs. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter.

Anticoagulants: Like other NSAIDs, aceclofenac may enhance the activity of anticoagulants.
Close monitoring of patients on combined anticoagulant and aceclofenac therapy should be undertaken.

Antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs): combined with NSAIDs may increase the risk of gastrointestinal bleeding.

Anti-diabetic agents: Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However, there have been isolated reports of hypoglycaemic and hyperglycaemic effects. Thus with aceclofenac, consideration should be given to adjustment of the dosage of hypoglycaemic agents.

Other NSAIDs: Concomitant therapy with acetylsalicylic acid and other NSAIDs may increase the frequency of side effects.

Quinolones: Due to an interaction between quinolones and NSAIDs, convulsions may occur. This can occur in patients with or without a history of convulsions or epilepsy.

Corticosteroids: increased risk of gastrointestinal ulceration or bleeding.

Cyclosporin, tacrolimus: Administration of NSAID drugs together with cyclosporin or tacrolimus is thought to increase the risk of nephrotoxicity due to decreased synthesis of prostacyclin in the kidney. During combination therapy it is therefore important to carefully monitor renal function.

Zidovudine: When NSAIDs are given with zidovudine there is an increased risk of haematological toxicity. There are indications of an increased risk of haemoarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

4.6 Fertility, pregnancy and lactation

Pregnancy:

There is no information on the use of aceclofenac during pregnancy. Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage, cardiac malformation or gastroschisis after use of prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5%. The risk is believed to increase with dose and duration of therapy.

In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, aceclofenac should not be given unless clearly necessary. If aceclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to: cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension); renal dysfunction, which may progress to renal failure with oligo-hydroamniosis; the mother and the neonate, at the end of pregnancy, to: possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.

inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, aceclofenac is contraindicated during the third trimester of pregnancy.

Lactation:

There is no information on the secretion of aceclofenac to breast milk; there was however no notable transfer of radio labelled (14C) aceclofenac to the milk of lactating rats.

The use of aceclofenac should therefore be avoided in pregnancy and lactation unless the potential benefits to the mother outweigh the possible risks to the foetus.

Fertility:
NSAIDs may impair fertility and are not recommended in women trying to conceive. The temporary discontinuation of aceclofenac should be considered in women having difficulties to conceive or undergoing investigations for infertility.

4.7 Effects on ability to drive and use machines
Patients suffering from dizziness, vertigo or other central nervous system disturbances while taking NSAIDs should refrain from driving or handling dangerous machinery.

4.8 Undesirable effects
Gastrointestinal: The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed.

The majority of side effects observed have been reversible and of a minor nature and include, gastro-intestinal
disorders (dyspepsia, abdominal pain, nausea and diarrhea) and occasional occurrence of dizziness.
Dermatological complaints including pruritus and rash and abnormal hepatic enzyme levels and raised serum
creatinine has occasionally been reported.

Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.

Bullous reactions including Stevens-Johns on syndrome and toxic epidermal necrolysis (very rare).

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke).

If serious side-effects occur, Aceclofenac Tablet should be withdrawn.
The following is a table of adverse reactions reported from clinical trials and post-authorisation use, grouped by system-Organ Classes and estimated frequencies.

MeDRa SOC	**Common <10% ->1%**	**Uncommon <1% ->0.1%**	**Rare <0.1% ->0.01%**	**Very rare/ isolated reports <0.01%**
Blood and lymphatic system disorders			Anaemia	Granulocytopenia Thrombocytopenia
Immune system			Anaphylactic	

disorders			reaction (including Shock) Hypersensitivity	
Metabolism and nutrition				Hyperkalemia
Psychiatric disorders				Depression Abnormal dreams Insomnia
Nervous system disorder	Dizziness			Paraesthesia Somnolence Headache Dysgeusia (Abnormal taste) Tremor
Eye disorders			Visual disturbance	
Ear and labyrinth disorders				Vertigo
Cardiac disorders			Cardiac failure	Palpitations
Vascular disorders			Hypertension	<?xml:namespace prefix = st1 ns = "urn:schemasmicrosoftcom: office:smarttags" /><st1:place w:st="on">Flushing</st1:place> Hot flush
Respiratory thoracic and mediastinal			Dyspnoea	
Gastrointestinal disorders	Dyspepsia Abdominal pain Nausea Diarrhoea	Flatulence Gastritis Constipation Vomiting Mouth ulceration	Melaena Gastrointestinal perforation	Stomatitis Haematemesis Peptic ulcer Gastrointestinal haemorrhage Hyperkalaemia
Skin and subcutaneous Tissue disorders		Pruritus Rash Dermatitis Urticaria	Face oedema	Purpura Serious mucocutaneous skin reactions
Renal and urinary disorders				Nephritic Syndrome
General disorders and administration site conditions				Oedema Fatigue
Investigations	Hepatic enzyme increased	Blood urea increased Blood creatinine increased		Blood alkaline phosphatase increased Weight increase Hyperkalaemia

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 requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

There is insufficient data available on the consequences of aceclofenac overdose in humans. The treatment of acute poisoning by non-steroid anti-inflammatory drugs basically consists of supportive and symptomatic treatment for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression.

Management of acute poisoning with oral aceclofenac consists of preventing absorption as soon as possible after overdose by means of gastric lavage and treatment with activated charcoal.

Forced diuresis, dialysis or haemoperfusion may not be able to eliminate NSAIDs due to their high rate of protein binding and extensive metabolism.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids.

ATC code: M01AB16

Aceclofenac is a non-steroidal substance with antiinflammatory and analgesic effects. Its mechanism of action is thought to be due to inhibition of prostaglandin synthesis.

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. Tmax 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.

Elimination:

The mean plasma elimination half-life is 4 – 4.3 hours. Clearance is estimated to 5 litres per hour. 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.

Aceclofenac is probably metabolized via CYP2C9 to the main metabolite 4'-OH-aceclofenac whose contribution to the clinical activity probably is negligible. Diclofenac and 4'-OHdiclofenac have been detected amongst many metabolites.

Characteristics in patients

No changes in the pharmacokinetics of aceclofenac have been detected in the elderly.

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 100 mg 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
Similarly, to other NSAIDs, aceclofenac is poorly tolerated by experimental animals. Additionally, pharmacokinetic differences between animals and man make it difficult to evaluate the potential toxicity of aceclofenac. However, toxicity studies employing maximally tolerated dosages in the rat, a species which metabolizes aceclofenac to diclofenac, and in the monkey (some exposure to unchanged aceclofenac) showed no other toxic effects than those commonly seen with NSAIDs.
Carcinogenicity studies in the mouse (systemic exposure to aceclofenac unknown) and in the rat (metabolism to diclofenac) did not show any carcinogenic effect and aceclofenac was negative in genotoxicity tests.

6. Pharmaceutical particulars
6.1 List of excipients
Magnesium stearate, Purified Talc, Sodium starch glycolate, Croscarmellose sodium, Crospovidone, Microcrystalline Cellulose, Mannitol, Maize Starch, Lactose Monohydrate, Povidone (As PVPK-30), Sodium Benzoate, Purified Water, Hypromellose (E-15), Purified Talc, Iso Propyl Alcohol, Dichloromethane, Colour: Titanium Dioxide, Polyethylene Glycol (As 6000) & Colour: Yellow Iron Oxide.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life: 36 months

6.4 Special precautions for storage:
Stored at a temperature not exceeding 30°C, in a cool and dark place, protect from direct sunlight.

6.5 Nature and contents of container
3 x 10 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 and other handling
Not applicable.

7. Marketing authorisation holder
Galaxy Pharmaceutical Ltd.
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Manufacturer
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8. Marketing Authorization Number
H2015/CTD2534/088

9. Date of first <Registration> / Renewal of the <Registration>
2026 September 02

10. Date of revision of the text
2026 September 02