SUMMARY OF PRODUCT CHARACTERISTICS
ACESTAR-100 (Aceclofenac Tablets 100 mg)

1. NAME OF THE MEDICINAL PRODUCT

ACESTAR-100 (Aceclofenac Tablets 100 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 100 mg aceclofenac BP.

Excipients with known effect:

Contains erythrosine (E127) as a colouring agent. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Pink coloured, round shaped, biconvex, film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aceclofenac is indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in adults.

4.2 Posology and method of administration

Adults

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

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

Elderly

The elderly are at increased risk of serious adverse reactions to NSAIDs, including gastrointestinal bleeding and perforation. If an NSAID is considered necessary, the lowest effective dose should be used and for the shortest possible duration. The pharmacokinetics of aceclofenac are not altered in elderly patients and dose modification is not therefore necessary.

Renal impairment

There is no evidence that dosage modification is required in patients with mild renal impairment, but caution should be exercised as with other NSAIDs. Aceclofenac is contraindicated in severe renal failure.

Hepatic impairment

There is evidence that the dose of aceclofenac should be reduced in patients with hepatic impairment. An initial daily dose of 100 mg is suggested.

Children

There are no clinical data on the use of aceclofenac in children and it is therefore not recommended for use in children.

Method of administration

Oral. The tablets should be swallowed whole with a sufficient quantity of liquid. To be taken preferably with or after food.

4.3 Contraindications

- Hypersensitivity to aceclofenac or to any of the excipients listed in section 6.1.
- Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).

- Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin, or other NSAIDs.
- Active bleeding or bleeding diathesis.
- Severe hepatic failure or severe renal failure.
- Established congestive heart failure (NYHA II–IV), ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
- History of gastrointestinal bleeding or perforation related to previous NSAID therapy.
- Third trimester of pregnancy. Aceclofenac should not be prescribed during pregnancy, especially during the last trimester, in women attempting to conceive or during lactation, unless there are compelling reasons for doing so.

4.4 Special warnings and precautions for use

General

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 COX-2 selective inhibitors should be avoided.

Gastrointestinal effects

Gastrointestinal bleeding, ulceration or perforation, which can be fatal, has 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 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 for patients requiring concomitant low-dose aspirin or other drugs likely to increase gastrointestinal risk. Patients with a history of GI toxicity should report any unusual abdominal symptoms, especially in the initial stages of treatment. When GI bleeding or ulceration occurs, treatment should be withdrawn.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants, SSRIs or antiplatelet agents.

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that aceclofenac, which is structurally related and metabolised to diclofenac, may be associated with an increased risk of arterial thrombotic events (myocardial infarction or stroke), particularly at high doses and with long-term treatment. 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. Patients with significant risk factors for cardiovascular events should only be treated with aceclofenac after careful consideration. Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild congestive heart failure.

Aceclofenac should also be administered with caution and under close medical surveillance to patients with a history of cerebrovascular bleeding.

Renal effects

The administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and precipitate renal failure. Patients at greatest risk are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. Renal function should be monitored regularly in these patients.

Hepatic effects

If abnormal liver function tests persist or worsen, or clinical signs consistent with liver disease develop, aceclofenac should be discontinued. Use in patients with hepatic porphyria may trigger an attack.

Dermatological effects

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely with NSAIDs. Aceclofenac should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. Aceclofenac should be avoided in varicella, as NSAIDs may worsen cutaneous and soft tissue infection complications.

Female fertility

The use of aceclofenac may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of aceclofenac should be considered.

SLE and mixed connective tissue disease

In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.

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

Haematological effects
Aceclofenac may reversibly inhibit platelet aggregation. It should be avoided in patients who have developed anaemia, agranulocytosis or thrombocytopenia secondary to NSAIDs or metamizol.

Long-term treatment
All patients receiving NSAIDs should be monitored for renal failure, hepatic function (elevation of liver enzymes may occur) and blood counts.

Erythrosine content
This medicinal product contains erythrosine (E127). Erythrosine may cause allergic reactions (including asthma) especially in patients with an allergy to aspirin.

4.5 Interaction with other medicinal products and other forms of interaction

Other NSAIDs including COX-2 inhibitors:

Avoid concomitant use of two or more NSAIDs (including aspirin at anti-inflammatory doses) as this may increase the risk of adverse effects including GI bleeding.

Anti-hypertensives (ACE inhibitors, ARBs):

Reduced antihypertensive effect. The risk of acute renal insufficiency may be increased in some patients when combined with NSAIDs. Use with caution, especially in the elderly. Ensure adequate hydration and monitor renal function.

Diuretics:

Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs. Serum potassium should be monitored when co-administered with potassium-sparing diuretics.

Digoxin and other cardiac glycosides:

NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels. Frequent monitoring of glycoside levels is required.

Lithium:

Several NSAIDs inhibit renal clearance of lithium, increasing serum lithium concentrations. Avoid combination unless frequent monitoring of lithium levels is performed.

Methotrexate:

NSAIDs may increase plasma levels of methotrexate, resulting in increased toxicity. Caution if NSAIDs and methotrexate are administered within 24 hours of each other. Monitor renal function when combination therapy is necessary.

Mifepristone:

NSAIDs should not be used for 8–12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Corticosteroids:

Increased risk of gastrointestinal ulceration or bleeding.

Anticoagulants (warfarin, heparin):

NSAIDs may enhance the effects of anticoagulants. Close monitoring of patients on combined anticoagulant and aceclofenac therapy is required.

Quinolone antibiotics:

Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

Antiplatelet agents and SSRIs:

Increased risk of gastrointestinal bleeding.

Ciclosporin and tacrolimus:

Increased risk of nephrotoxicity due to decreased synthesis of prostacyclin in the kidney. Careful monitoring of renal function is important.

Zidovudine:

Increased risk of haematological toxicity. There is evidence of an increased risk of haemarthroses and haematoma in HIV-positive haemophiliacs.

Antidiabetic agents:

Isolated reports of hypoglycaemic and hyperglycaemic effects have been reported with NSAIDs and antidiabetic agents. Consideration should be given to adjustment of the dosage of hypoglycaemic agents during concomitant therapy.

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 embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage, cardiac malformation and gastroschisis after use of prostaglandin synthesis inhibitors in early pregnancy. From the 20th week of pregnancy onward, aceclofenac use may cause oligohydramnios resulting from foetal renal dysfunction, which may occur shortly after treatment initiation and is usually reversible upon discontinuation. Reports of ductus arteriosus constriction following treatment in the second trimester have also been received.

During the first and second trimester, aceclofenac should not be given unless clearly necessary. If used, the dose should be kept as low and duration as short as possible, and antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after several days of exposure from gestational week 20 onward. Aceclofenac should be discontinued if oligohydramnios or ductus arteriosus constriction are found.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to: cardiopulmonary toxicity (premature constriction/closure of the ductus arteriosus and pulmonary hypertension); renal dysfunction which may progress to renal failure with oligohydramnios. At the end of pregnancy, they may cause prolonged bleeding time and inhibition of uterine contractions resulting in delayed or prolonged labour. Consequently, aceclofenac is contraindicated during the third trimester of pregnancy.

Breast-feeding

There is no information on the secretion of aceclofenac into breast milk; however, there was no notable transfer of radiolabelled aceclofenac to the milk of lactating rats. The use of aceclofenac should be avoided during lactation unless the potential benefits to the mother outweigh the possible risks to the infant.

Fertility

The use of aceclofenac may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of aceclofenac should be considered.

4.7 Effects on ability to drive and use machines

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

Summary of the safety profile

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, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, and exacerbation of colitis and Crohn's disease have been reported. Cardiovascular and cerebrovascular adverse events, including oedema, hypertension and arterial thrombotic events, have been reported in association with NSAID treatment. Pancreatitis has been reported very rarely.

Tabulated list of adverse reactions

Frequencies: common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

System Organ Class	Common	Uncommon	Rare	Very Rare / Isolated Reports
Blood and lymphatic disorders			Anaemia	Bone marrow depression, granulocytopenia, thrombocytopenia, neutropenia, haemolytic anaemia
Immune system disorders			Anaphylactic reaction	

System Organ Class	Common	Uncommon	Rare	Very Rare / Isolated Reports
			(including shock), hypersensitivity	
Metabolism and nutrition disorders				Hyperkalaemia
Psychiatric disorders				Depression, abnormal dreams, insomnia
Nervous system disorders	Dizziness			Paraesthesia, tremor, somnolence, headache, dysgeusia
Eye disorders			Visual disturbance	
Ear and labyrinth disorders				Vertigo, tinnitus
Cardiac disorders			Cardiac failure	Palpitations
Vascular disorders			Hypertension	Flushing, hot flush, vasculitis
Respiratory disorders			Dyspnoea	Bronchospasm, stridor
Gastrointestinal disorders	Dyspepsia, abdominal pain, nausea, diarrhoea	Flatulence, gastritis, constipation, vomiting, mouth ulceration	Melaena, GI haemorrhage, GI ulceration	Stomatitis, intestinal perforation, exacerbation of Crohn's disease and ulcerative colitis, haematemesis, pancreatitis
Hepatobiliary disorders	Hepatic enzyme increased			Hepatic injury (including hepatitis), jaundice, alkaline phosphatase increased
Skin and subcutaneous tissue disorders		Pruritus, rash, dermatitis, urticaria	Angioedema	Purpura, severe mucocutaneous skin reaction (SJS, TEN), photosensitivity
Renal and urinary disorders		Blood urea increased, blood creatinine increased		Renal failure, nephrotic syndrome
General disorders				Oedema, fatigue, cramps in legs

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 the National Regulatory Authority.

4.9 Overdose

Symptoms: headache, nausea, vomiting, epigastric pain, gastrointestinal irritation, gastrointestinal bleeding, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, hypotension, respiratory depression, fainting and occasionally convulsions. In cases of significant poisoning, acute renal failure and liver damage are possible.

Management: Patients should be treated symptomatically. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, gastric lavage may be considered within one hour of ingestion of a potentially life-threatening overdose. Dialysis or haemoperfusion are of no benefit due to high protein binding. Good urine output should be ensured. Renal and liver function should be monitored. Patients should be observed for at least four hours after ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Phenylacetic acid derivative; non-steroidal anti-inflammatory and antirheumatic drug. ATC code: M01AB16.

Mechanism of action: Aceclofenac works by inhibiting the action of cyclooxygenase (COX) enzymes involved in the production of prostaglandins, which are responsible for pain, swelling, inflammation and fever. Aceclofenac is structurally related and is partially metabolised to diclofenac; its principal active metabolite 4'-hydroxyaceclofenac also contributes to the anti-inflammatory effect.

5.2 Pharmacokinetic properties

Absorption

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.

Distribution

Aceclofenac penetrates into the synovial fluid, where concentrations reach approximately 57% of those in plasma. Volume of distribution approximately 25 litres. Mean plasma elimination half-life around 4 hours. Aceclofenac is highly protein-bound (>99%).

Metabolism

4'-Hydroxyaceclofenac is the main metabolite detected in plasma. Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites. Aceclofenac is partially metabolised to diclofenac. No changes in pharmacokinetics have been detected in the elderly.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, local tolerance, genotoxicity, carcinogenic potential and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the film-coated tablet:

No.	Excipient	Specification
1	Maize starch	BP
2	Microcrystalline cellulose	BP
3	Povidone K 30	BP
4	Purified water	BP
5	Purified talc	BP
6	Magnesium stearate	BP
7	Sodium starch glycolate	BP
8	Colloidal anhydrous silica	BP
9	Croscarmellose sodium	BP
10	Hydroxypropylmethylcellulose (HPMC 15 cps)	BP
11	Titanium dioxide	BP
12	Erythrosine (E127) (excipient with known effect)	IH
13	Isopropyl alcohol	BP
14	Methylene chloride	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container

10 tablets packed in one ALU-ALU blister; 3 such blisters packed in one carton with package insert. Pack size: 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ZAIN PHARMA LTD.

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Go-Down No. 1, 2, 3, Off Mombasa Road,

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P.O. Box: 100167-00101, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

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