SUMMARY OF PRODUCT CHARACTERISTICS
ZOFENAC 100 (Diclofenac Sodium BP 100 mg Film-Coated Tablets)

1. NAME OF THE MEDICINAL PRODUCT

ZOFENAC 100 (Diclofenac Sodium BP 100 mg Film-Coated Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains diclofenac sodium BP 100 mg.

Excipients with known effect:

Contains Sunset Yellow FCF (E110). For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Orange, round, biconvex film-coated tablet, plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ZOFENAC 100 is indicated for the symptomatic treatment of pain and inflammation in: inflammatory and degenerative forms of rheumatism including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis; periarthritis humeroscapularis; acute musculoskeletal disorders; post-operative pain; dental pain; primary dysmenorrhoea; acute gout.

4.2 Posology and method of administration

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

Adults

Recommended initial daily dose 100–150 mg. In milder cases and for long-term therapy, 75–100 mg daily is usually sufficient. Total daily dose should be given in two or three divided doses. Maximum daily dose is 150 mg.

Elderly

Elderly patients are at greater risk. If treatment is necessary, the lowest effective dose should be used for the shortest possible duration with regular GI bleeding monitoring.

Paediatric population

Not recommended for children and adolescents below 18 years of age.

Renal impairment

Contraindicated in severe renal impairment (CrCl <30 ml/min). Use with caution in mild to moderate renal impairment.

Hepatic impairment

Contraindicated in severe hepatic impairment. Use lowest effective dose in mild to moderate impairment with hepatic function monitoring.

Method of administration

Oral. Swallow whole with sufficient liquid; do not chew or crush. Preferably taken with or after food.

4.3 Contraindications

- Hypersensitivity to diclofenac sodium or to any of the excipients listed in section 6.1.
- History of GI bleeding or perforation related to previous NSAID therapy.
- Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes).
- Third trimester of pregnancy.
- Severe hepatic or renal failure.
- Active bleeding or bleeding disorders; blood dyscrasias; bone marrow depression.

- Established congestive heart failure (NYHA II–IV), ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
- Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other NSAIDs.

4.4 Special warnings and precautions for use

Gastrointestinal effects

GI bleeding, ulceration or perforation — which can be fatal — has been reported at any time during treatment, with or without warning symptoms. Risk is highest with increasing doses, history of ulcer (particularly complicated), and in the elderly. These patients should start on the lowest dose and protective agents (misoprostol or PPIs) should be considered.

Cardiovascular and cerebrovascular effects

Appropriate monitoring is required for patients with hypertension and/or mild to moderate congestive heart failure. Epidemiological and clinical trial data suggest that use of diclofenac — particularly at high dose (150 mg/day) and in long-term treatment — may be associated with a small increased risk of arterial thrombotic events.

Renal effects

NSAIDs can precipitate renal impairment. Patients at highest risk are those with pre-existing renal dysfunction, cardiac impairment, liver dysfunction, diuretic users and the elderly.

Hepatic effects

Close surveillance is necessary in patients with hepatic impairment; liver enzymes should be monitored if abnormalities persist.

Dermatological effects

Serious skin reactions (exfoliative dermatitis, Stevens-Johnson syndrome, TEN) have been reported very rarely. Discontinue diclofenac at the first appearance of skin rash, mucosal lesions or any sign of hypersensitivity.

Sunset Yellow FCF (E110)

This product contains Sunset Yellow FCF (E110), an azo dye that may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Diuretics and antihypertensives:

NSAIDs may reduce their effect; co-administration may result in deterioration of renal function.

Lithium and digoxin:

NSAIDs may increase plasma concentrations; monitor levels.

Methotrexate:

Caution if NSAIDs and methotrexate are administered within 24 hours of each other.

Anticoagulants and antiplatelet agents:

Concomitant use may increase the risk of bleeding.

Ciclosporin:

NSAIDs may increase nephrotoxicity; monitor renal function.

SSRIs:

Increased risk of GI bleeding.

Quinolone antibiotics:

Increased risk of convulsions.

Other NSAIDs and corticosteroids:

Increased frequency of GI adverse effects.

4.6 Fertility, pregnancy and lactation

Pregnancy

ZOFENAC 100 should not be given during the first and second trimesters unless clearly necessary. It is contraindicated during the third trimester (risk of premature closure of ductus arteriosus, renal dysfunction, prolonged bleeding time, delayed labour).

Breast-feeding

Diclofenac passes into breast milk in small amounts. Should not be administered during breast-feeding.

Fertility
Use of NSAIDs may impair female fertility and is not recommended in women attempting to conceive.

4.7 Effects on ability to drive and use machines
Dizziness, drowsiness, somnolence and fatigue may occur. Patients should not drive or operate machinery if affected.

4.8 Undesirable effects

System Organ Class	Common	Uncommon	Rare/Very rare
Gastrointestinal	Dyspepsia, abdominal pain, nausea, diarrhoea, vomiting	Flatulence, gastritis, constipation	Melaena, GI haemorrhage, ulceration, perforation, pancreatitis
Hepatobiliary	Elevated hepatic enzymes		Hepatitis, jaundice, hepatic failure
Nervous system	Dizziness, headache, vertigo	Somnolence, fatigue	Paraesthesia, aseptic meningitis
Cardiac/vascular			Cardiac failure, palpitations, MI, vasculitis
Skin		Rash, pruritus, urticaria	SJS, TEN, angioedema, photosensitivity
Immune system			Anaphylactic reaction (including shock)
Renal			Renal failure, interstitial nephritis, nephrotic syndrome
Haematological			Agranulocytosis, aplastic anaemia, thrombocytopenia

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
No typical clinical picture from diclofenac overdosage. Symptoms may include vomiting, GI haemorrhage, diarrhoea, dizziness, tinnitus or convulsions; in significant poisoning, acute renal and liver damage are possible. Treatment is symptomatic. Activated charcoal within one hour of ingestion should be considered. Specific therapies such as dialysis are unlikely to be helpful due to high protein binding.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroidal; acetic acid derivatives and related substances. ATC code: M01AB05.

Diclofenac sodium is a phenylacetic acid derivative NSAID with anti-inflammatory, analgesic and antipyretic properties. It inhibits cyclooxygenase (COX-1 and COX-2) enzymes, thereby inhibiting the synthesis of prostaglandins, thromboxanes and prostacyclins from arachidonic acid.

5.2 Pharmacokinetic properties

Absorption: Diclofenac is rapidly and almost completely absorbed from the GI tract. Bioavailability of diclofenac from modified-release (retard) tablets is approximately 82% of an equivalent gastro-resistant tablet dose. Distribution: Protein binding 99.7% (mainly albumin). Volume of distribution 0.12–0.17 L/kg. Penetrates well into synovial fluid. Biotransformation: Glucuronidation and hydroxylation to phenolic metabolites, most converted to glucuronide conjugates. Two phenolic metabolites are biologically active but to a lesser extent. Elimination: Plasma half-life 1–2 hours; approximately 60% excreted in urine as metabolites, remainder via bile in faeces; <1% excreted unchanged.

5.3 Preclinical safety data

No special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, local tolerance, genotoxicity, carcinogenic potential and reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch, di-basic calcium phosphate, purified talc, purified water (manufacturing solvent), magnesium stearate, sodium starch glycolate, colloidal anhydrous silica, isopropyl alcohol (manufacturing solvent), Wincoat WT N 1092 Sunset Yellow (E110; film-coating mixture), methylene chloride (manufacturing solvent).

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

ALU-PVC blister packs containing 10 tablets per blister. Cartons containing 10 blisters (100 tablets) with package insert.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ZAIN PHARMA LTD.

Plot No. 209/13741, Colchester Park,

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

Behind Nice and Lovely House,

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

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD11720/24993

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

14.04.2026

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