SUMMARY OF PRODUCT CHARACTERISTICS
ZOFENAC 50 (Diclofenac Sodium Tablets 50 mg)

1. NAME OF THE MEDICINAL PRODUCT

ZOFENAC 50 (Diclofenac Sodium Film-Coated Tablets 50 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 50 mg diclofenac sodium BP.

Excipients with known effect:

Contains sunset yellow (as Wincoat WT N 1092 Sunset Yellow) 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.

Orange coloured, round, biconvex, film-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of inflammatory and degenerative forms of rheumatism including: rheumatoid arthritis; osteoarthritis including spondylarthritis; periarthritis humeroscapularis.

Relief of pain and inflammation in other conditions, including acute gout, acute musculoskeletal disorders, post-traumatic and post-operative pain and inflammation, and primary dysmenorrhoea.

4.2 Posology and method of administration

Adults

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

The recommended dose is 100–150 mg daily in divided doses (50 mg two to three times daily). The maximum recommended daily dose is 150 mg.

Elderly

The elderly are at increased frequency of adverse reactions. The lowest effective dose should be used.

Renal impairment

Diclofenac is contraindicated in severe renal failure. Caution should be exercised in patients with mild to moderate renal impairment.

Hepatic impairment

Diclofenac is contraindicated in severe hepatic failure. Caution should be exercised in patients with hepatic impairment.

Paediatric population

ZOFENAC 50 (50 mg tablet) is not appropriate for use in children.

Method of administration

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

4.3 Contraindications

- Known hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Patients who have experienced asthma, urticaria, or allergic-type reactions after taking acetylsalicylic acid or other NSAIDs (cross-reactivity risk).
- History of gastrointestinal bleeding or perforation, related to previous NSAID therapy.
- Active, or history of, recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).

- 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.

4.4 Special warnings and precautions for use

General

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

Gastrointestinal effects

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment. Patients at greatest risk include the elderly, patients with a prior history of serious GI events, and those taking concomitant anticoagulants, SSRIs, antiplatelet agents, or corticosteroids. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients. The lowest effective dose should be used and the patient monitored for GI symptoms.

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of diclofenac, particularly at high doses (150 mg daily) and in long-term treatment, may be associated with a modestly increased risk of arterial thrombotic events (myocardial infarction or stroke). Diclofenac shares these cardiovascular risks with other selective COX-2 inhibitors and non-selective NSAIDs. Patients with significant risk factors for cardiovascular events (hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with diclofenac after careful consideration and with the lowest effective dose for the shortest duration. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.

Renal and hepatic effects

The administration of diclofenac 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 in these patients. Hepatic effects: Abnormal liver function tests may occur. If abnormal liver function tests persist or worsen, or clinical signs consistent with liver disease develop (including elevation of serum transaminases, cholestatic jaundice), diclofenac should be discontinued.

SLE and mixed connective tissue disease

Diclofenac sodium should be administered with caution to patients suffering from systemic lupus erythematosus and mixed connective tissue disease; there may be an increased risk of aseptic meningitis.

Female fertility

As with other NSAIDs, the use of diclofenac may impair female 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 diclofenac should be considered.

Sunset yellow content

This medicinal product contains sunset yellow (E110). Sunset yellow may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Diuretics and antihypertensives (ACE inhibitors, ARBs, beta-blockers):

NSAIDs including diclofenac may reduce the effect of antihypertensives and diuretics. The risk of acute renal insufficiency, usually reversible, may be increased in some patients with compromised renal function when ACE inhibitors, ARBs and/or diuretics are combined with NSAIDs. Ensure adequate hydration; monitor renal function.

Lithium:

NSAIDs may inhibit the renal clearance of lithium, resulting in elevated serum lithium concentrations. Monitor lithium levels.

Methotrexate:

NSAIDs may reduce the excretion of methotrexate, potentially increasing toxicity. Exercise caution if NSAIDs and methotrexate are administered within 24 hours of each other.

Ciclosporin:

Diclofenac may increase the nephrotoxicity of ciclosporin due to effects on renal prostaglandins.

Anticoagulants and antiplatelet agents:

Concomitant administration could increase the risk of bleeding. Close monitoring is recommended; INR should be monitored in patients receiving warfarin.

Corticosteroids and other NSAIDs (including aspirin at anti-inflammatory doses):

Concomitant administration may increase the frequency of gastrointestinal adverse effects. Concomitant aspirin may decrease plasma diclofenac concentrations without compromising clinical efficacy; however, the combination increases GI risk.

Antidiabetics:

Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However, isolated reports of hypoglycaemic and hyperglycaemic effects have been received; dosage adjustment of hypoglycaemic agents may be needed.

SSRIs:

Increased risk of gastrointestinal bleeding when combined with NSAIDs.

Quinolone antibiotics:

Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics.

4.6 Fertility, pregnancy and lactation

Pregnancy

During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. The dose should be kept as low and duration as short as possible. From the 20th week of pregnancy onward, NSAIDs including diclofenac may cause oligohydramnios resulting from foetal renal dysfunction. If used after 20 weeks of gestation, limit use to the lowest effective dose for the shortest duration; antenatal monitoring for oligohydramnios is advisable. Diclofenac is contraindicated in the third trimester of pregnancy.

Breast-feeding

Like other NSAIDs, diclofenac passes into breast milk in small amounts. Diclofenac should not be administered during breast-feeding in order to avoid undesirable effects in the infant.

Fertility

As with other NSAIDs, the use of diclofenac may impair female fertility. In women who have difficulty conceiving or who are undergoing investigation of infertility, withdrawal of diclofenac should be considered.

4.7 Effects on ability to drive and use machines

Patients who experience visual disturbances, dizziness, vertigo, somnolence, CNS disturbances, drowsiness or fatigue while taking NSAIDs should refrain from driving or operating machinery.

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions are gastrointestinal in nature. GI bleeding, ulceration or perforation, sometimes fatal, particularly in the elderly, may occur. Cardiovascular events (oedema, hypertension, cardiac failure) have also been reported in association with NSAID treatment. Frequencies: common (≥1/100 to <1/10); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

System Organ Class	Common	Rare / Very Rare
Nervous system disorders	Dizziness, headache	Paraesthesia, drowsiness (rare)
Ear and labyrinth disorders	Vertigo	Tinnitus (rare)
Gastrointestinal disorders	Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain	Gastritis, GI haemorrhage, haematemesis, haemorrhagic diarrhoea, GI ulcer (rare)
Hepatobiliary disorders		Hepatic enzyme increased, hepatitis, jaundice (rare)
Skin and subcutaneous tissue disorders		Rash, urticaria, photosensitivity, SJS, TEN (very rare)
Renal and urinary disorders		Interstitial nephritis, nephrotic syndrome, acute renal failure (rare)
Blood and lymphatic disorders		Thrombocytopenia, leucopenia, anaemia (rare); aplastic anaemia (very rare)

System Organ Class	Common	Rare / Very Rare
Immune disorders		Anaphylactic/anaphylactoid reactions including hypotension and shock (rare)
Cardiovascular disorders		Oedema, hypertension, cardiac failure (rare); palpitations, chest pain, MI (very rare)

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
There is no typical clinical picture resulting from diclofenac overdosage. Overdosage can cause symptoms such as vomiting, gastrointestinal haemorrhage, diarrhoea, dizziness, tinnitus or convulsions. In the event of significant poisoning, acute renal failure and liver damage are possible.

Management
Treatment should be symptomatic and supportive. Specific therapies such as dialysis or haemoperfusion are probably of no help due to high protein binding. Good urine output should be ensured; renal and liver function should be closely monitored.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids, acetic acid derivatives and related substances. ATC code: M01AB05.

Diclofenac sodium is a phenylacetic acid derivative with anti-inflammatory, analgesic and antipyretic properties. Inhibition of prostaglandin biosynthesis is considered fundamental to its mechanism of action, primarily through inhibition of cyclooxygenase (COX) enzymes.

5.2 Pharmacokinetic properties

Absorption
Diclofenac sodium is rapidly and well absorbed from the gastrointestinal tract. The systemic availability of diclofenac from film-coated tablets is approximately 82% of an equal dose administered as gastro-resistant tablets, probably as a result of rate-dependent first-pass effect.

Distribution
Diclofenac is bound to serum proteins at a rate of 99.7%, mainly to albumin (99.4%). The apparent volume of distribution is 0.12–0.17 l/kg.

Biotransformation
Biotransformation takes place partly by glucuronidation of the intact molecule, but mainly by single and multiple hydroxylation and methoxylation, resulting in several phenolic metabolites, most of which are converted to glucuronide conjugates. Two phenolic metabolites are biologically active, but to a smaller extent than diclofenac.

Elimination
Total systemic clearance in plasma is 263 ± 56 ml/min. The terminal plasma half-life is 1–2 hours. About 60% of the administered dose is excreted in the urine as metabolites; less than 1% as unchanged substance. The remainder is eliminated through the bile in the faeces.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, genotoxicity, repeated-dose toxicity and reproductive toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No.	Excipient
1	Maize starch
2	Dibasic calcium phosphate
3	Purified talc
4	Purified water
5	Magnesium stearate
6	Sodium starch glycolate
7	Colloidal anhydrous silica
8	Isopropyl alcohol
9	Wincoat WT N 1092 Sunset Yellow (excipient with known effect — contains sunset yellow E110)
10	Methylene chloride

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-PVC blister; 10 such blisters packed in one carton with package insert. Pack size: 100 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.
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)
H2025/CTD11719/24990

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14.12.2025

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