Summary of Product Characteristics

1. Name of the medicinal product
ADIFAN 50 (Diclofenac Sodium Tablets 50 mg)

2. Qualitative and Quantitative composition
Each film coated tablet contains 50mg Diclofenac Sodium.

3. Pharmaceutical form

Tablets
Orange Colour, Round shape, Biconvex film coated Tablets.

4.CLINICAL PARTICULARS:
4.1 Therapeutic indications

Relief of all grades of pain and inflammation in in a wide range of conditions, including:
(i) arthritic conditions: rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout,
(ii) acute musculo-skeletal disorders such as periarthritis (for example frozen shoulder), tendinitis, tenosynovitis, bursitis,
(iii) other painful conditions resulting from trauma, including fracture, low back pain, sprains, strains, dislocations, orthopaedic, dental and other minor surgery.

4.2 Posology and method of administration Posology
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4 Special warnings and precautions for use).

Adults: One 100 mg diclofenac sodium prolonged-release tablet daily. If necessary, the daily dosage can be increased to 150 mg by supplementation with the conventional dosage forms containing diclofenac sodium 25 mg or 50 mg.
The recommended maximum daily dose of diclofenac sodium is 150mg.

Special populations
Paediatrics:
This medicine is not suitable for children.

Elderly:

Although the pharmacokinetics of Diclofenac sodium are not impaired to any clinically relevant extent in elderly patients, nonsteroidal anti-inflammatory drugs should be used with particular caution in such patients who generally are more prone to adverse reactions. In particular it is recommended that the lowest effective dosage be used in frail elderly patients or those with a low body weight (see also precautions) and the patient should be monitored for GI bleeding during NSAID therapy.

Cardiovascular and significant cardiovascular risk factors

Diclofenac is contraindicated in patients with established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease (see section 4.3 Contraindications).

Patients with congestive heart failure (NYHA-I) or significant risk factors for cardiovascular disease should be treated with diclofenac only after careful consideration. Since cardiovascular risks with diclofenac may increase with dose and duration of exposure, the lowest effective daily dose should be used and for the shortest duration possible (see section 4.4 Special warnings and precautions for use).

Renal impairment: Diclofenac is contraindicated in patients with renal failure (see section 4.3 Contraindications).

No specific studies have been carried out in patients with renal impairment, therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering diclofenac to patients with mild to moderate renal impairment (see section 4.4 Special warnings and precautions for use).

Hepatic impairment: Diclofenac is contraindicated in patients with hepatic failure (see section 4.3 Contraindications). No specific studies have been carried out in patients with hepatic impairment, therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering diclofenac to patients with mild to moderate hepatic impairment (see section 4.4 Special warnings and precautions for use).

Method of administration

For oral administration.

To be taken whole with liquid, preferably with or after food.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Active, gastric or intestinal ulcer, bleeding or perforation.

- History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy
- Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding)
- Last trimester of pregnancy (see section 4.6 Fertility, pregnancy and lactation).
- Hepatic failure
- Renal failure
- Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease
- Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac is also contraindicated in patients in whom attacks of asthma, angiodema, urticarial or acute rhinitis are precipitated by ibuprofen, acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs.

4.4 Special warnings and precautions for use

- Undesirable effects may be minimized by using the minimum effective dose for the shortest duration necessary to control symptoms.
- Diclofenac sodium should be administered with caution to patients suffering from systemic lupus erythematosus and mixed connective tissue disease.
- The use of diclofenac sodium, as with any drug known to inhibit cyclooxygenase/prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive.
- In women who have difficulty conceiving or are undergoing investigation of infertility, withdrawal of diclofenac sodium should be considered.
- Gastrointestinal bleeding (haematemesis, melaena) ulceration or perforation which can be fatal has been reported with all NSAIDs including diclofenac, and may occur at any time during treatment, with or without warning symptoms or a previous history of serious GI events. They generally have more serious consequences in the elderly. If gastrointestinal bleeding or ulceration occurs in patients receiving diclofenac, the drug should be withdrawn.
- Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, and generalised bullous fixed drug eruption have been reported very rarely in association with the use diclofenac (see section 4.8 Undesirable effects). Patients appear to be at the 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.
- In patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (i.e. nasal polyps), chronic obstructive pulmonary diseases or chronic infections of the respiratory tract (especially if linked to allergic rhinitis-like symptoms),

reactions on NSAIDs like asthma exacerbations (so called intolerance to analgesics / analgesics asthma), Quincke's oedema or urticaria are more frequent than in other patients. Therefore, special precaution is recommended in such patients (readiness for emergency).

4.5 Interaction with other medicinal products and other forms of interaction

Diuretics and antihypertensive agents: NSAIDs including diclofenac may reduce the effect of diuretics and antihypertensive medicinal products.

Ciclosporin: Diclofenac, like other NSAIDs, may increase the nephrotoxicity of ciclosporin due to the effect on renal prostaglandins.

Anticoagulants and anti-platelet agents: Caution is recommended since concomitant administration could increase the risk of bleeding.

Antidiabetics: Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect.

Other NSAIDs and corticosteroids: Concomitant administration of diclofenac together with other systemic NSAIDs or corticosteroids may increase the frequency of gastrointestinal undesirable effects. Concomitant administration of acetylsalicylic acid decreases the plasma concentration of diclofenac, without
Compromising clinical efficacy.

Anticoagulants and anti-platelet agents: Caution is recommended since concomitant administration could increase the risk of bleeding.

Lithium: If used concomitantly, diclofenac may increase plasma concentrations of lithium. Monitoring of the serum lithium level is recommended.

Digoxin: If used concomitantly, diclofenac may raise plasma concentrations of digoxin. Monitoring of the serum digoxin level is recommended.

Methotrexate: Diclofenac can inhibit the tubular renal clearance of methotrexate hereby increasing methotrexate levels.

Cardiac glycosides: Concomitant use of cardiac glycosides and NSAIDs in patients may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

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

4.6 Fertility, pregnancy and lactation

Summary of Product Characteristics

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 difficulties conceiving or who are undergoing investigation of infertility, withdrawal of diclofenac should be considered.

Pregnancy:

During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac 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.

Breast-feeding:

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

4.7 Effects on ability to drive and use machines

Dizziness, drowsiness, visual disturbances, vertigo, somnolence central nervous system disturbances or fatigue are possible undesirable effects after taking NSAIDs, if affected; patients should not drive or operate machinery

4.8 Undesirable effects

Adverse reactions are ranked under the heading of frequency, the most frequent first, using the following convention: very common: (>1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10,000); not known: cannot be estimated from available data.

The following undesirable effects include those reported with other short-term or long-term use.

Table 1

Blood and lymphatic system disorders	
Very rare	Thrombocytopenia, leucopoenia, anaemia (including haemolytic and aplastic anaemia), agranulocytosis.
Immune system disorders	
Rare Very rare	Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock). Angioneurotic oedema (including face oedema).
Psychiatric disorders	

Very rare	Disorientation, depression, insomnia, nightmare, irritability, psychotic disorder.
Nervous system disorders	
Common Rare Very rare not known	Headache, dizziness. Somnolence, tiredness. Paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident. Confusion, hallucinations, disturbances of sensation, malaise.
Eye disorders	
Very rare not known	Visual disturbance, vision blurred diplopia. Optic neuritis.
Ear and labyrinth disorders	
Common Very rare	Vertigo. Tinnitus, hearing impaired.
Cardiac disorders	
Uncommon*	Myocardial infarction, cardiac failure, palpitations, chest pain.
not known	Kounis syndrome.
Vascular disorders	
Very rare	Hypertension, hypotension, vasculitis.
Respiratory, thoracic and mediastinal disorders	
Rare Very rare	Asthma (including dyspnoea). Pneumonitis.
Gastrointestinal disorders	
Common Rare Very rare not known	Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia. Gastritis, gastrointestinal haemorrhage, haematemesis, diarrhoea haemorrhagic, melaena, gastrointestinal ulcer with or without bleeding or perforation (sometimes fatal particularly in the elderly). Colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis (including ulcerative stomatitis), glossitis,

	oesophageal disorder, diaphragm-like intestinal strictures, pancreatitis. Ischaemic colitis.
Hepatobiliary disorders	
Common Rare Very rare	Transaminases increased. Hepatitis, jaundice, liver disorder. Fulminant hepatitis, hepatic necrosis, hepatic failure.
Skin and subcutaneous tissue disorders	
Common Rare Very rare not Known	Rash. Urticaria. Bullous eruptions, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura , allergic purpura, pruritus. Fixed drug eruption, generalised bullous fixed drug eruption.
Renal and urinary disorders	
Very rare	Acute renal failure, haematuria, proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis.
Reproductive system and breast disorders	
Very rare	Impotence.
General disorders and administration site conditions	
Rare	Oedema.

** The frequency reflects data from long-term treatment with a high dose (150mg/day).*

Clinical trial and epidemiological data consistently point towards an increased risk of arterial thrombotic events (for example myocardial infarction or stroke) associated with the use of diclofenac, particularly at high dose (150 mg daily) and in long term treatment (see sections 4.3 and 4.4 for Contraindications and Special warnings and special precautions for use).

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 Pharmacovigilance electronic reporting systems

Summary of Product Characteristics

4.9 Overdose

Symptoms

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

Therapeutic measure

Management of acute poisoning with NSAIDs, including diclofenac, essentially consists of supportive measures and symptomatic treatment. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression.

Special measures such as forced diuresis, dialysis or haemo-perfusion are probably of no help in eliminating NSAIDs, including diclofenac, due to high protein binding and extensive metabolism.

Activated charcoal may be considered after ingestion of a potentially toxic overdose, and gastric decontamination (e.g. vomiting, gastric lavage) after ingestion of a potentially life threatening overdose.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacodynamic group: Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids

ATC Code: M01AB05 Mechanism of action

ADIFAN 100 contains the prostaglandin synthetase inhibitor diclofenac sodium.Thisis a phenylacetic acid derivative with anti-inflammatory, analgesic and antipyretic properties.

Inhibition of prostaglandin biosynthesis is considered fundamental toits mechanism of action.

5.2 Pharmacokinetic properties

Absorption

It can be deducted from the renal elimination of diclofenac and its hydroxylated metabolites that proportionally the same amount of diclofenac is released and

resorbed from diclofenac sodiumretard tablets as from the gastro-resistant tablets. Probably as a result of a rate depending first pass effect the systemic availability of diclofenac from diclofenac retard tablets is about 82% of an equal dose administered as gastro resistant tablets.

Distribution

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

Biotransformation

The biotransformation of diclofenac takes place partly by glucuronidation of the intact molecule, but mainly by single and multiple hydroxylation and methoxylation, resulting in several phenolic metabolites (3'-hydroxy-, 4'-hydroxy, 5'-hydroxy, 4',5'-dihydroxy-, 3'-hydroxy-4'-
methoxydiclofenac), most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, but to a smaller extent than diclofenac. **Excretion**
The total systemic clearance of diclofenac in plasma is 263 ± 56 ml/min (mean value ± SD). The terminal half-life in plasma is 1-2 hours. About 60% of the administered dose is excreted in the urine in the form of metabolites from one of these processes; less than 1% is excreted as unchanged substance. The remainder of the dose is eliminated as metabolites through the bile in the faeces.

5.3 Preclinical safety data None stated.

6. Pharmaceutical particulars

6.1 List of excipients

Summary of Product Characteristics

SR. NO.	INGREDIENTS	SPECIFICATION
1	Di-Basic Calcium Phosphate	BP
2	Maize Starch	BP
3	Purified Talc	BP
4	Purified Water	BP
5	Magnesium Stearate	BP
6	Sodium Starch Glycolate	BP
7	Colloidal Anhydrous Silica	BP
8	Isopropyl Alcohol	BP
9	Wincoat WT N 1092 Sunset Yellow	IH
10	Methylene chloride	BP

6.3 Shelf life 36 months.

6.4 Special precautions for storage
Store at the temperature not exceeding 30°C. Protect from light and moisture. Keep medicines out of reach of children.

6.5 Nature and contents of container
10 Tablets packed in one ALU-PVC blister and such10 blister packed in one carton with insert.

6.6 Special precautions for disposal and other handling
No special requirements

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER
Marketing Authorization Holder:
Medina Chemical Remedies, Mombasa Road,
Gateway Park, P.O BOX 47346-00100,
Nairobi Kenya.

8. Marketing Authorization Number:
CTD11825

9. Date of First

1st May,2026

10. Date of Revision of the Text:

1st May,2026