SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Product name: ARTIMED TABLET (Gastro- resistant Diclofenac Tablets BP 50 mg)

Strength :50mg

Pharmaceutical Form: Enteric Coated Tablet for oral use s

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Each Enteric coated tablet Contains:

Diclofenac Sodium B.P 50 mg

Excipients q.s.

Excipient(s) with known effect: Lactose Monohydrate

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Enteric Coated Tablet

Brick red colour biconvex enteric coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, ankylosing spondylitis, osteo-arthrosis, painful post-operative and post-traumatic inflammation and swelling and dysmenorrhoea.

4.2 Posology and method of administration

Usual Adult Dose: 50 mg taken three times daily. The tablet must be taken whole during or after meals. Initially this dose may be increased to 150 mg daily and may be reduced to 75 to 100 mg daily in milder cases or for long-term and maintenance therapy. Diclofenac sodium is not recommended for use in children as safety and efficacy have not been established.

4.3 Contraindications

Diclofenac sodium is contra-indicated in patients with known hypersensitivity to diclofenac and in patients who respond to aspirin and aspirin-type drugs with sensitivity reactions like asthma, acute rhinitis and urticaria. Diclofenac sodium is absolutely contraindicated in patients with peptic ulceration or a history of such ulceration and should be used with caution in patients with renal or hepatic insufficiency.

4.4 Special warnings and precautions for use

ARTIMED should be given with care to patients with bleeding disorders, cardiovascular diseasesand in those who are receiving coumarin anticoagulants. Patients who are sensitive to aspirin generally should not be given **ARTIMED**.

4.5 Interaction with other medicinal products and other forms of interaction

Serious interactions have been reported after the use of high dose methotrexate with diclofenac. Blood concentrations of lithium are increased when ARTIMED is administered concomitantly Concomitant treatment with cimetidine may inhibit the metabolism of the mebendazole in the liver, resulting in increased plasma concentrations of the drug especially during prolonged treatment. In the latter case, determination of plasma concentrations is recommended in order to allow dose adjustments. In patients receiving high doses of mebendazole for treatment of tissue – dwelling organisms such as Echinococcus multi locularis, carbamazepine has been shown to lower mebendazole plasma concentrations by induction of hepatic microsomal enzymes and to impair the therapeutic response.

4.6 Fertility, pregnancy and lactation

The safe use of **ARTIMED** in pregnancy has not been demonstrated. Regular use of NSAID's during the third trimester of pregnancy may result in premature closure of the foetal ductus arteriosus in utero and possibly in persistent pulmonary hypertension of the newborn. The onset of labour may be delayed and its duration increased.

4.7 Effects on ability to drive and use machines

Patients who experience dizziness, drowsiness, fatigue or visual disturbances, while taking NSAIDS should refrain from driving or operating machinery.

4.8 Undesirable effects

In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Gastric or intestinal ulceration with associated bleeding has been reported – ARTIMED therapy should be discontinued immediately in such cases. Skin rashes and gastro-intestinal disturbances may occur. Headache, dizziness, oedema, nervousness, pruritus, tinnitus, insomnia, blurred vision and other ocular reactions, peripheral oedema, malaise, jaundice, elevated transaminase levels, drowsiness and hypersensitivity reactions (eg. bronchospasm) have occurred. Blood counts and monitoring of hepatic and renal function are advised during prolonged therapy with ARTIMED as blood dyscrasias have been reported.

4.9 Overdose

Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs and may occur following an overdose. Patients should be managed by symptomatic and supportive care following a NSAID overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose). Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antimalarials, Blood Schizontocide

ATC code: P01 BF01.

Mechanism of action

Diclofenac sodium is a non-steroidal compound, a phenylacetic acid derivative, with analgesic, antipyretic and anti-inflammatory effects. Diclofenac sodium inhibits the biosynthesis and release of prostaglandins, which are known to be implicated in the pathogenesis of inflammation, pain and fever. ARTIMED Tablets are enteric-coated so that absorption occurs in the gastrointestinal tract to give peak plasma concentrations approximately 2 hours after ingestion. There is at least 99% binding to plasma-proteins and excretion of metabolites is mainly in the urine.

5.2 Pharmacokinetics:

Diclofenac sodium is rapidly absorbed from the gut and is subject to first-pass metabolism. Tablets give peak plasma concentrations after 1-4 hours. The active substance is 99.7% protein bound and plasma half-life for the terminal elimination phase is 1-2 hours. Diclofenac sodium enters the synovial fluid, where maximum concentrations are measured 2-4 hours after the peak plasma values have been obtained. The apparent half-life for elimination from the synovial fluid is 3-6 hours. Two hours after reaching the peak plasma values, concentrations of the active substance are already higher in the synovial fluid than they are in the plasma, and they remain higher for up to 12 hours. Approximately 60% of the administered dose is excreted via the kidneys in the form of metabolites and less than 1% in unchanged form. The remainder of the dose is excreted via the bile in metabolised form. In patients with impaired renal function no accumulation of diclofenac sodium has been reported.

5.3 Preclinical safety data

There are no pre-clinical data of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients(s)

Sr. No.	**Name of excipients**
1	Dibasic Calcium Phosphate
2	Lactose Monohydrate
3	Starch

4	Methyl Paraben
5	Propyl Paraben
6	Magnesium Stearate
7	Sodium Starch Glycollate
8	Talcum Powder
9	Purified Water
10	Medicoat EN 5001
11	Isopropyl Alcohol
12	Methylene Chloride

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years 24 Months

6.4 Special precautions for storage

Store in dry place, below 30^0C. Protect from Light. Keep out of the reach of Children.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

10 tablets packed in ALU/PVC Blister and such 10 blisters packed in monocarton with pack insert.

6.6 Special precautions for disposal <and other handling>

Not Applicable.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

05620/07604/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:02/12/2016

Date of latest renewal: 01/02/20201

10. DATE OF REVISION OF THE TEXT

24/07/2023