SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name : **Adiflam-SR Tablet**
1.2 Generic Name : Prolonged Release Diclofenac Tablet BP
1.3 Strength : Diclofenac Sodium BP 100mg/Tab.
1.4 Pharmaceutical Form : Tablet

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each Prolonged Release film-coated tablet contains:
Diclofenac Sodium BP 100 mg

3. PHARMACEUTICAL FORM

Tablet
Orange coloured round, biconvex, prolonged release film coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prolonged Release Diclofenac Tablet BP is indicated for rheumatoid arthritis, osteoarthritis, Low back pain, ankylosing spondylitis, gout, acute musculoskeletal disorders, periarthritis (frozen shoulder), tendinitis, tenosynovitis, bursitis, sprains, dislocations, painful postoperative conditions, pain following dental surgery & painful inflammatory conditions in gynaecology.

4.2 Posology and method of administration

Prolonged Release Diclofenac Tablet BP may not be taken more than once a day.

4.3 Contraindications

Prolonged Release Diclofenac Tablet BP is contra- indicated in patients with known hypersensitivity to Diclofenac Sodium or in patients with severe or active peptic ulceration.

4.4 Special warnings and special precautions for use

Diclofenac Sodium Tablet is used with caution in patients with impairment of hepatic, renal or cardiac function, blood coagulation disorders, recent proctitis, G.I. disorders & in children.

4.5 Interaction with other FPPs and Other forms of Interaction

ACE Inhibitors: Increased risk of renal impairment when NSAIDs given with ACE inhibitors, also hypotensive effect antagonized. Adrenergic Neurone Blockers: NSAIDs antagonise hypotensive effect of adrenergic neurone blocker. Beta Blockers: NSAIDs antagonise hypotensive effect of Beta blocker. Cardiac Glycosides: NSAIDs possibly increase the plasma concentration of cardiac glycosides, also possible exacerbation of heart failure and reduction of renal function. Diuretics: Risk of nephrotoxicity of NSAID increased by diuretics.

4.6 Pregnancy and lactation

Pregnancy: Avoid the use of NSAIDs during pregnancy unless the potential benefits outweigh the risk. NSAIDs should be avoided during the trimester because use is associated with a risk of closure of fetal ductus arterious in utero and possible persistent pulmonary hypertension of the new born. In addition, the onset of labour may be delayed and its duration may be increased.

Breast-Feeding: NSAIDs should be used with caution during breast-feeding.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Gastro-intestinal disturbances including discomfort, nausea, diarrhoea, and occasionally bleeding and ulceration occur. Systemic as well as local effects of NSAIDs contribute to gastro-intestinal damage, taking oral formulation with milk or food or using enteric coated formulation or changing the route of administration may only partially reduce symptoms such as dyspepsia.

4.9 Overdose & Treatment

Overdose: There is no typical clinical picture resulting from diclofenac over dosage. Over dosage can cause symptoms such as headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, diarrhoea, dizziness, disorientation, excitation, coma, drowsiness, tinnitus, fainting or convulsions. In the case of significant poisoning acute renal failure and liver damage are possible.

Treatment: 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

Pharmacotherapeutic group: NSAID & Analgesic.

It is an inhibitor of prostaglandin synthetase, (cyclo-oxygenase). Diclofenac sodium in vitro does not suppress proteoglycan biosynthesis in cartilage at concentrations equivalent to the concentrations reached in human beings.

5.2 Pharmacokinetic properties

Absorption is complete but onset is delayed until passage through the stomach, which may be affected by food which delays stomach emptying. The active substance is 99.7% protein bound, mainly to albumin (99.4%). 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, most of which are converted to glucuronide conjugates. About 60% of the administered dose is excreted in the urine in the form of the glucuronide conjugate of the intact molecule and as metabolites, most of which are also converted to glucuronide conjugates. Less than 1% is excreted as unchanged substance. The rest of the dose is eliminated as metabolites through the bile in the faeces.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Lactose	BP
02.	Microcrystalline Cellulose (102)	BP
03.	Hypromellose (HPMC)	BP
04.	Povidone (PVPK-30)	BP
05.	Isopropyl Alcohol	BP
06.	Magnesium Stearate	BP
07.	Purified Talc (Talcum)	BP
Film Coating		
08.	Hypromellose (HPMC)	BP
09.	Colour Titanium Dioxide (77891)	BP
10.	Macrogol-4000 (P.E.G-4000)	BP
11.	Ethyl cellulose	BP
12.	Diethyl Phthalate	BP
13.	Lake Sunset Yellow	IH
14.	Purified Talc (Talcum)	BP
15.	Dichloromethane (Methylene Chloride)	BP
16.	Methanol	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Protect from light. Keep away from moisture. Keep out of reach of children. Do not chew or crush the tablet. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

a. 10 blisters of 10 tablets packed in an inner carton. (10's x 10)
b. 10 blisters of 20 tablets packed in an inner carton. (10x20)
c. 1 blister of 10 tablets packed in a mono pack, such 20 mono packs packed in an outer carton. (10 x 1 x 20).

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

07175/08327/REN/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Mar 4, 2022

10. DATE OF REVISION OF THE TEXT

01/01/2023