Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

SUFASOFORT Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablets contains: 500 mg of Paracetamol and 50 mg of Diclofenac Sodium

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of soft tissue injuries with spasm and inflammation, Neck / shoulder / back pain, Tendonitis / tenosynovitis / bursitis, Musculoskeletal disorders.

4.2 Posology and method of administration

Adults: Adults – 1 tablet 3 times daily or as directed by the Physician.
Method of Administration: Oral

4.3 Contraindications

Contraindicated in patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Contains Paracetamol.

Do not take anything else containing paracetamol while taking this medicine.

Talk to your doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

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

The use of Diclofenac with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors, should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects.

Caution is indicated in the elderly on basic medical grounds. In particular it is recommended that the lowest effective dosage be used in frail elderly patients or those with a low body weight.

Like other NSAIDs, Diclofenac may mask the signs and symptoms of infection due to its pharmacodynamic properties.

The use of diclofenac potassium 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 potassium should be considered.

4.5 Interaction with other medicinal products and other forms of interaction

Diclofenac may increase the plasma concentrations of lithium, digoxin and methotrexate. It may increase the activity of anticoagulants, inhibit the activity of diuretics, enhance cyclosporine nephrotoxicity and precipitate convulsions when co-administered with quinolone antibiotics.

The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce hepatic microsomal enzymes. Co-administration of paracetamol with rifampicin, isoniazid, chloramphenicol, antiepileptic drugs and antiviral drugs is to be avoided. Metoclopromide may increase the absorption of paracetamol whereas excretion and plasma concentration may be altered when co- administered with probenecid. Cholestyramine also reduces the absorption of paracetamol.

4.6 Pregnancy and lactation

Not recommended in pregnant and lactating women.

4.7 Effects on ability to drive and use machines

Not known

4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia purpura, methaemoglobenaemia and agranulocytosis, but these were not necessarily causality related to paracetamol.

Adverse effects of Diclofenac are most commonly observed are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of coilitis and Crohn's disease have been reported. Less frequently, gastritis has been observed.

4.9 Overdose

Overdosage may cause nausea, vomiting, pain abdomen, dizziness, somnolence, headache, sweating, pancreatitis, hepatic failure and acute renal failure.

Treatment, if required, includes gastric lavage, activated charcoal and other symptomatic measures as per medical advice.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diclofenac Potassium- Antiinflammatory and Antirheumatic Products, Non-Steroids.

Paracetamol- Analgesics and Antipyretics

ATC code: Diclofenac Potassium - M01AB05, Paracetamol- N02BE01

Diclofenac is a NSAID with anti-inflammatory, analgesic and antipyretic properties. It is rapidly and almost completely absorbed when administered as an oral dose. Food does not have a significant effect on the extent of oral absorption. At therapeutic concentrations it is more than 99% bound to plasma proteins. Diclofenac and/or its metabolites are rapidly and preferentially taken up and retained in inflamed tissues. It penetrates synovial fluid where concentrations may persist even when plasma concentrations fall. The terminal half-life is about 1 to 2 hours. Diclofenac acts by inhibiting cyclooxygenase, thus prevents the formation of prostaglandins, the mediators of inflammation. It also inhibits lipoxygenase thus preventing the synthesis of leukotrienes. Thus, it acts on both the pathways and is a very potent anti-inflammatory drug/ medicine.

Paracetamol is an effective analgesic-antipyretic (relieves mild to moderate pain) and a weak anti-inflammatory agent. Paracetamol reduces fever by a direct action on the heat regulating centres to increase the dissipation of heat. It is readily absorbed from the g.i. tract with peak plasma concentrations occurring about 10 to 60 min. after oral administration. It is distributed into most body tissues.

5.2 Pharmacokinetic properties <u>Paracetamol:</u>

<u>Absorption and Fate</u>

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause liver damage.

<u>Diclofenac</u>

Absorption:

Diclofenac is rapidly and completely absorbed from the tablets. The absorption sets in immediately after administration and the same amount is absorbed as from an equivalent dose of diclofenac sodium gastro-resistant tablets. Mean peak plasma concentrations of 3.8 µmol/L are attained after 20 - 60 minutes after ingestion of one tablet of 50mg. Ingestion together with food has no influence on the amount of diclofenac absorbed although onset and rate of absorption may be slightly delayed.

Since about half of diclofenac is metabolized during its first passage through the liver ("first pass" effect), the area under the concentration curve (AUC) is about half as large following oral or rectal administration as it is following a parenteral dose of equal size.

The amount absorbed is in linear proportion to the size of the dose.

Pharmacokinetic behaviour does not change after repeated administration. No accumulation occurs provided the recommended dosage intervals are observed.

Distribution:

The active substance is 99.7% protein bound, mainly to albumin (99.4%).

Diclofenac enters the synovial fluid, where maximum concentrations are measured 2-4 hours after peak plasma values have been attained. 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 remain higher for up to 12 hours.

Diclofenac was detected in a low concentration (100 ng/mL) in breast milk in one nursing mother. The estimated amount ingested by an infant consuming breast milk is equivalent to a 0.03 mg/kg/day dose.

Biotransformation/Metabolism:

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. Two phenolic metabolites are biologically active, but to a much lesser extent than diclofenac.

Elimination:

Total systemic clearance of diclofenac in plasma is 263±56mL/min (mean value ± SD). The terminal half-life in plasma is 1-2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1-3 hours.

About 60% of the administered dose is excreted in the urine as 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

It is a well-established drug for which there are adequate published data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose	BP
Maize Starch	BP
Gelatin	BP
Methyl Paraben Sodium	BP
Propyl Paraben Sodium	BP
Purified Water	BP
Isopropyl Alcohol	BP
Povidone	BP
Sodium Starch Glycollate	BP
Colloidal Silicon Dioxide	BP
Purified Talc	BP
Magnesium Stearate	BP

6.2 Incompatibilities None

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light & moisture.

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

Alu-PVC Blister of 10 tablets, such 10 blisters are packed in primary carton along with pack insert.

6.6 Special precautions for disposal <and other handling> No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

KNVM MEDICARE PVT. LTD

KH. 959, opposite Reliance, Udyog Kunj,

Ghaziabad (UP)

Manufacturer
Magbro Healthcare
India

8. MARKETING AUTHORISATION NUMBER

FDA/SD.243-050681

9. DATE OF FIRST AUTHORISATION OR RENEWAL

16TH MAY,2027

10. DATE OF REVISION OF THE TEXT

08/2025