Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Lysoflam Tablets

2. Qualitative and quantitative composition
Each film coated tablet contains:
Paracetamol BP.....500 mg
Diclofenac Potassium BP .....50 mg
Serratiopeptidase (Enteric Coated) .....15 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Film coated tablet
Pale yellow oblong film-coated tablets having bisecting line on one side and visible colour of Serratiopeptidase enteric coated granules.

4. Clinical particulars

4.1 Therapeutic indications
Acute painful & inflammatory conditions.

4.2 Posology and method of administration
Posology
Adult & Children (12 years and above): One twice daily.

Method of administration
Oral Tablets.

4.3 Contraindications
Diclofenac is contraindicated in patients with peptic ulcers, asthma Paracetamol is contraindicated in patients with hepatic dysfunction.

4.4 Special warnings and precautions for use
Risk of GI ulceration, bleeding & perforation with NSAID therapy. Severe GI toxicity such as GI ulceration, bleeding & perforation, can occur at any time with or without any warning symptoms , in patients treated chronically with NSAIDS.Caution should be exercised when diclofenac administered chronically.

4.5 Interaction with other medicinal products and other forms of interaction
Diclofenac, Serratiopeptidase should not be taken concomitantly with other NSAIDs, anticoagulants including low-dose/ LMW heparin, sucralfate, triamterene, cyclosporine, cholestyramine, colestipol, digoxin, aspirin, methotrexate and lithium whereas Paracetamol reduces the absorption of cholestyramine within 1 hour of administration whereas it accelerates the absorption with metoclopramide.

4.6 Pregnancy and Lactation

Pregnancy

Category C

The use of Lysoflam in pregnancy is not recommended.

Lactation

Lysoflam should be administered to lactating woman only if potential benefits justify the risk to the infants.

Others:

Paracetamol should be used with caution in patients with anemia.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

4.8 Undesirable effects

Lysoflam is generally well tolerated, but may cause mild nausea, vomiting, dyspepsia, skin rashes and hepatic disturbances.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems to the respective National Regulatory Authorities.

4.9 Overdose

Following acute overdose, toxicity may result. Symptoms include GI irritation with erosion & hemorrhage or perforation, kidney damage, liver damage , heart damage ,hemolytic anemia , agranulocytosis , thrombocytopenia , aplastic anemia & meningitis .over symptoms may include headache , dizziness ,tinnitus confusion , blurred vision , mental disturbance , skin rash , stomatitis , edema , reduces renal sensitivity , corneal deposits & hyperkalemia.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: analgesic, anti-inflammatory and anti-pyretic action.

Diclofenac potassium

Lysoflam tablets contain the potassium salt of diclofenac, a nonsteroidal compound with pronounced and clinically demonstrable analgesic, anti-inflammatory and anti-pyretic properties. Diclofenac is a potent inhibitor of prostaglandin biosynthesis and modulator of arachidonic acid release and uptake. Lysoflam tablets have a rapid onset of action and are therefore suitable for the treatment of acute episodes of pain and inflammation. In migraine attacks Lysoflam has been shown to be effective in relieving the headache and in improving the accompanying

symptom of nausea. Diclofenac in vitro does not suppress proteoglycan biosynthesis in cartilage at concentrations equivalent to the concentrations reached in human beings.

Paracetamol
The antipyretic effect of Paracetamol is attributed to its ability to inhibit COX in the brain where peroxide tone is low. Recent evidence suggests inhibition of COX-3 (believed to be splice variant product of the COX-1 gene) could represent a primary central mechanism by which Paracetamol decreases pain and possibly fever.

Serratiopeptidase
Serratiopeptidase is a proteolytic enzyme available for clinical use more than a decade. It binds to alpha2-macroglobulin in the blood in the ratio of 1:1 which helps to mask its antigenicity but retains its enzymatic activity and is slowly, transferred to site of inflammation. Serratiopeptidase hydrolyses bradykinin, histamine and serotonin responsible for oedematic status. It reduces swelling improves microcirculation & expectoration of sputum etc. Thus it can be concluded that serratiopeptidase has antiinflammatory, anti-oedemic and fibrinolytic activity and acts rapidly on localized inflammation. Diclofenac, paracetamol and serratiopeptidase combined together provide effective relief from pain and inflammation.

5.2 Pharmacokinetic properties

Pharmacotherapeutic group: analgesic, anti-inflammatory and anti-pyretic action.

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5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. Pharmaceutical Particulars

6.1 List of Excipients

Maize Starch BP
Microcrystalline cellulose BP
Magnesium stearate BP
Purified Talc BP
Color Tartrazine IH
Sodium Starch Glycollate BP
Methyl Hydroxybenzoate BP
Propyl Hydroxybenzoate BP
Opadry II (85G52193) Yellow IH
Purified Water BP

6.2 Incompatibilities

Not applicable

6.3 Shelf-Life

24 Months

6.4 Special Precautions for storage

Store in a dry place, below 30^{o}C. Protect from light.
Keep out of reach of children

6.5 Nature and Content of container

Alu–PVC Blister pack of 1 x 10 Tablets packed in mono carton along with pack insert.
Alu–PVC Blister pack of 3x 10 Tablets packed in mono carton along with pack insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder

Cachet Pharmaceuticals Pvt. Ltd
415, Shah Nahar Industrial Estate,
Dr. E. Moses Road, Worli, Mumbai-400 018
Maharashtra, India.

8. Marketing Authorization Number
H2009/19973/558

9. Date of first authorization/renewal of the authorization
22/10/2008

10. Date of revision of the text
15/06/2026