SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

ACECOR SP TABLETS

2. Quality and Quantitative Composition

Each film coated tablet contains:
Paracetamol BP 500 mg
Aceclofenac BP 100 mg
Serratiopeptidase 15 mg
(as enteric coated 30,000 units of Serratiopeptidase)

Colour: Sunset Yellow lake and Titanium Dioxide
For Excipients see section 6.1

3. Pharmaceutical Dosage Form:

Film coated tablet
Orange coloured, oblong shaped, film coated tablets having a half line mark on one side and plain on other side.

4. Clinical Particulars

4.1 Therapeutic indications:

ACECOR SP Tablets is indicated for:

- Trauma Surgery: In sports injuries, sprains, laceration, fractures, dislocation and osteoarthritis etc.
- Surgery: To reduce post-operative edema at injection sites, internal tissue edema and inflammation caused at post-operative handling.
- Plastic Surgery: For diminishing post-operative edema, restoring micro-circulation at the site of graft and minimizing risk of graft rejection along with reduction in pain.
- Infections: Facilitating mucolysis in sinuses, ear cavities and coupled with anti-inflammatory activity in upper respiratory tract affections helps in faster resolution, better antimicrobial availability in infected tissues and faster cures.
- Dermatology: Particularly useful in acutely painful inflamed dermatoses.
- Dentistry: Helps better control over dental infections and inflammation.
- Obstetrics & Gynecology: The anti-inflammatory and anti-edema activity helps in resolution of post-partum hematomas, breast engorgements and pregnancy-related thrombophlebitis.

4.2 Posology and method of administration:

Posology

Adults: One Tablet daily, 1-2 hours after meals, or as prescribed by the Physician.

Method of administration:

Oral.

4.3 Contraindications
ACECOR SP Tablets is contraindicated in patients with hypersensitivity to any of the ingredients, in those known to have bronchospasm or acute rhinitis or urticaria with aspirin or similar agents, presence of active or suspected peptic ulcer, gastrointestinal or other active bleeding, bleeding disorders, severe heart or kidney or liver failure. It is not advocated in children, and during pregnancy and lactation.

4.4 Special warning and precautions for use:
ACECOR SP Tablets should be administered with caution in patients with acid-peptic disease, inflammatory bowel disease, impaired renal or liver functions, blood dyscrasias, SLE, porphyria, hematopoietic and coagulation disorders, and in patients with hypersensitivity to aspirin or other NSAIDs. Aceclofenac is to be advocated with due caution in those on diuretics, or otherwise at risk of hypovolemia. It should be used in pregnant women and nursing mothers only if absolutely required. Data on safety and efficacy of aceclofenac in children is not adequate. In those receiving long-term
ACECOR SP Tablets, periodical monitoring of renal and hepatic functions and blood counts is necessary. Intake of alcohol with ACECOR SP Tablets must be with due precaution.

4.5 Interaction with other medicinal products and other forms of Interactions:
Aceclofenac could interact with oral thrombolytics, diuretics, cyclosporine, tacrolimus, phenytoin, digoxin, cimetidine, tolbutamide, phenylbutazone, amiodarone, miconazole, sulfaphenazole, methotrexate, lithium, and highly protein-bound drugs. Serratiopeptidase can increase ease the action of anticoagulant drugs.

4.6 Fertility, Pregnancy and lactation
Aceclofenac should not be used in pregnant women and nursing mothers unless the potential benefit to the patient outweighs the potential risk to the foetus.

4.7 Effects on ability to drive and use Machines:
None known

4.8 Undesirable effects:
The most common side effects are gastric pain, flatulence, nausea. vomiting, diarrhoea & dyspepsia; rarely peptic ulcer and gastrointestinal bleeding occur. Infrequently, hypersensitivity reactions, skin reactions, taste perversion, malaise, change in appetite and weight, edema, palpitations, flushing, purpura and eye disorders are possible due to aceclofenac. Neurological reactions possible include headache, drowsiness, insomnia, irritability and mood disturbances. Aceclofenac and paracetamol can rarely cause hepatitis, renal dysfunction and blood dyscrasias.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorization of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse

reactions to the marketing authorization holder or, where applicable, via the national reporting system https://pv.pharmacyboardkenya.org/

4.9 Overdosage:
Symptoms of aceclofenac overdose include headache, nausea, vomiting, epigastric pain, gastrointestinal irritation, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, hypotension, respiratory depression, fainting, occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.
Treatment: within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least four hours after ingestion of potentially toxic amounts. In case of frequent or prolonged convulsions, patients should be treated with intravenous diazepam. Management of acute poisoning with NSAIDs essentially consists of supportive and symptomatic measures. Paracetamol hepatotoxicity is the most common cause of acute liver failure. Untreated overdose can lead to liver failure and death within days. Treatment is aimed at removing the paracetamol from the body and replacing glutathione. Activated charcoal can be used to decrease absorption of paracetamol if the patient presents for treatment soon after the overdose. While the antidote, acetylcysteine acts as a precursor for glutathione, helping the body regenerate enough to prevent damage to the liver, a liver transplant is often required if damage to the liver becomes severe.
Symptoms of serratiopeptidase overdose is nausea, vomiting, anorexia, epigastric discomfort. In some cases the symptoms of overdose are blood streaks in sputum and bleeding. The treatment is symptomatic.

5. Pharmacological Properties:
5.1 Pharmacodynamic Properties:
Aceclofenac
Aceclofenac is a non-steroidal agent with marked anti-inflammatory and analgesic properties. The mode of action of aceclofenac is largely based on the inhibition to prostaglandin synthesis.
Aceclofenac is a potent inhibitor of the enzyme, cyclo-oxygenase, which is involved in the production of prostaglandins.

Paracetamol
Paracetamol is a non-opiate para-aminophenol derivative that exhibits analgesic and antipyretic activity. It does not possess anti-inflammatory activity.

Serratiopeptidase
Serratiopeptidase binds to 2-macroglobulin in the blood in a 1:1 ratio. This helps to mask its antigenicity but retains its enzymatic activity. Levels of serratiopeptidase are slowly transferred to the exudates at the site of infection and inflammation and gradually blood

levels decline. The mechanism of action of Serratiopeptidase appears to be hydrolysis of histamine, bradykinin and serotonin, and a proteolytic and fibrinolytic effect. Primarily this is achieved by dissolving the complement (specific proteins responsible for inflammation) and increasing the plasmin activity by inhibiting the plasmin inactivators. By the aforementioned mechanisms, Serratiopeptidase reduces capillary permeability induced by histamine, bradykinin and serotonin; breaks down abnormal exudates and proteins; facilitates the absorption of decomposed products through blood and lymphatics. Thus, Serratiopeptidase promotes wound healing and repair, and restore the skin temperature of the inflamed area, burn or trauma to normal.

5.2 Pharmacokinetic Properties:

Aceclofenac

After oral administration, aceclofenac is rapidly and completely absorbed as unchanged drug. Peak plasma concentrations are reached approximately 1.25 to 3.00 hours following ingestion.

Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The volume of distribution is approximately 25 L. The mean plasma elimination half-life is around 4 hours. Aceclofenac is highly protein-bound (>99%).

Aceclofenac circulates mainly as unchanged drug. 4'-hydroxyaceclofenac is the main metabolite detected in plasma.

Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxyl metabolites. No changes in the pharmacokinetics of aceclofenac have been detected in the elderly.

Paracetamol

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the half-life in plasma is 1 to 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 50% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses, 90 to 100% of

the drug may be recovered in the urine within the first day. However, practically no paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation.

Serratiopeptidase

Serratiopeptidase has been shown to be absorbed from the digestive tract. On oral administration, it is absorbed unchanged into the systemic circulation, from where it penetrates into all the tissues. It reaches higher concentrations in the inflamed tissues. It attains peak levels in one hour.

5.3 Preclinical safety Data:

The results from preclinical studies conducted with aceclofenac are consistent with those expected for NSAIDs. The principal target organ was the gastro-intestinal tract. No unexpected findings were recorded. Aceclofenac was not considered to have any mutagenic

activity in three in vitro studies and an in vivo study in the mouse. Aceclofenac was not found to be carcinogenic in either the mouse or rat. Paracetamol None stated.

6. Pharmaceutical Particulars:

6.1 List of excipients:

Ethyl Cellulose BP
Dichloromethane BP
Isopropyl Alcohol BP
Maize Starch BP
Povidone K - 30 USP
Sodium Methyl Paraben BP
Sodium Propyl Paraben BP
Sodium Metabisulphate BP
Magnesium Stearate BP
Purified Talc BP
Microcrystaline Cellulose BP
Hydroxy Propyl Methyl Cellulose (HPMC15 CPS) BP
Titanium Dioxide BP
Colour Sunset Yellow Lake
Purified Water BP

6.2 Incompatibilities:

None

6.3 Shelf life:

36 Months

6.4 Special precautions for storage:

Store below 30°C in a dry place. Protect from light.
Keep medicine out of reach of children.

6.5 Nature and contents of container:

10 tablets are packed in Alu-Alu blister. Such 3 blisters are packed in a carton along with insert.

6.6 Special Precaution for Disposal and other handling:

None

7. Marketing Authorization Holder:

Signature Healthcare Ltd.,
Cape Business Park, Along Thika Super Highway,
P.O.Box 66172-00800, Nairobi, Kenya.

8. Marketing Authorization Numbers:

H2022/CTD9678/20566

9. Date of first authorization/renewal of the authorization:
17/04/2023

10. Date of revision of the text:
17/04/2023