Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

ZULU-ES TABLET

2. Qualitative and quantitative composition

Each film coated tablet contains: Aceclofenac BP 100mg, Paracetamol BP 500mg. Esomeprazole Magnesium Trihydrate USP Eq. to Esomeprazole 20mg (As Enteric Coated)

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated Tablet.

A white color oblong shape biconvexed film coated tablet, scored in the middle on one side and plain on other side of the tablet.

4. Clinical particulars

4.1 Therapeutic indications

Aceclofenac and Paracetamol film-coated tablets are indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. Esomeprazole is used for the treatment of erosive reflux esophagitis.

4.2 Posology and method of administration

Taken as one dose (every 24 hours) or as directed by physician. It is not recommended for use in children.

Method of administration: Oral.

Tablets should be swallowed whole with a sufficient quantity of liquid.

4.3 Contraindications

Hypersensitivity to Aceclofenac and Paracetamol or to any of the excipients listed. NSAIDS are contraindicated in patients who have previously shown hypersensitivity reactions (eg. Asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin, or other non-steroidal anti-inflammatory drugs. Esomeprazole should not be used concomitantly with nelfinavir.

4.4 Special warnings and precautions for use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. The use of Aceclofenac and Paracetamol with concomitant NSAIDs including cyclooxygenase- 2 selective inhibitors should be avoided. Patients on long-term treatment of Esomeprazole (particularly those treated for more than a year) should be kept under regular surveillance.

4.5 Interaction with other medicinal products and other forms of interaction

Other analgesics including cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects including GI bleeding. Anti-hypertensives: NSAIDs, may reduce the effect of activity antihypertensives. The risk of acute renal insufficiency which is usually reversible, may be increased in some patients with compromised renal function (e.g. dehydrated patients or elderly patients) when ACE-

inhibitors or angiotensin II receptor antagonists are combined with NSAIDs. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter. Gastric acid suppression during treatment with esomeprazole and other PPIs might decrease or increase the absorption of medicinal products with a gastric pH dependent absorption.

4.6 Fertility, Pregnancy and lactation

The use of Tablets should be avoided in pregnancy and lactation unless the potential benefits to the other outweigh the possible risks to the foetus.

4.7 Effects on ability to drive and use machines

Undesirable effects such as dizziness, vertigo, drowsiness, fatigue, visual disturbances or other central nervous system disorders are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

The most commonly-observed adverse events 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 colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed. Pancreatitis has been reported very rarely.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacy and Poisons Board-Pharmacovigilance Electronic Reporting System (PvERS); https://pv.pharmacyboardkenya.org .

4.9 Overdose

Symptoms 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: Patients should be treated symptomatically as required. 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. Specific therapies such as, dialysis or haemoperfusion are probable of no help in eliminating NSAIDs due to

their high rate of protein binding and extensive metabolism. Good urine output should be ensured.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Aceclofenac and Paracetamol is a non-steroidal agent with marked anti-inflammatory and analgesic properties. The mode of action of Aceclofenac and Paracetamol is largely based on the inhibition to prostaglandin synthesis. Aceclofenac and Paracetamol is a potent inhibitor of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins. Esomeprazole is the S-isomer of omeprazole and reduces gastric acid secretion through a specific targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell. Both the R- and S-isomer of omeprazole have similar pharmacodynamic activity.

5.2 Pharmacokinetic properties

Absorption: After oral administration, Aceclofenac and Paracetamol is rapidly and completely absorbed as unchanged drug. Peak plasma concentrations are reached approximately 1.25 to 3.00 hours following ingestion. Absorption of esomeprazole is rapid, with peak plasma levels occurring approximately 1-2 hours after dose.

Distribution: Aceclofenac and Paracetamol penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The volume of distribution is approximately 25 L. The apparent volume of distribution at steady state in healthy subjects is approximately 0.22 l/kg body weight. Esomeprazole is 97% plasma protein bound.

Metabolism: Aceclofenac and Paracetamol circulates mainly as unchanged drug. 4′-hydroxyAceclofenac and Paracetamol is the main metabolite detected in plasma. Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites. Esomeprazole is completely metabolised by the cytochrome P450 system (CYP).

Elimination: The mean plasma elimination half-life is around 4 hours. Aceclofenac and Paracetamol is highly protein- bound (>99%). Esomeprazole is completely eliminated from plasma between doses with no tendency for accumulation during once-daily administration.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Maize Starch
Microcrystalline Cellulose
Povidone K30
Colloidal Anhydrous Silica
Magnesium Stearate
Eudragit L30D 55
Tab Coat White

Isopropyl Alcohol
Dichloromethane
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Commercial Presentation: 4's, 10's, 20's, 30's & 100's
1 x 10's (10 tablets are packed in one PVC-Blister and one PVC-Blister is kept in one carton along with package insert).

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorization holder

INNOCIA LIFESCIENCES PVT. LTD.,
Address: Block A, No.12, Balaji Nagar, Ambattur, Chennai-600 053
Country: INDIA.

8. Marketing Authorization number(s)

H2022/CTD9636/21457

9. Date of first registration / Renewal of the registration

2023 March 28

10. Date of revision of the text:

2023 March 28