Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Kaluma Strong Caplets (Paracetamol, Aspirin, Caffeine Tablets)

STRENGTH

Each uncoated tablet contains:

Paracetamol BP.....200 mg

Aspirin BP.....400 mg

Caffeine Anhydrous BP.....50 mg

Excipients.....q.s.

PHARMACEUTICAL FORM

Caplets (Oral)

2. Qualitative and quantitative composition
*Evaporates during the manufacturing process.

For a full list of excipients, see section 6.1

3. Pharmaceutical form
Caplets (Oral)

4. Clinical particulars
4.1 Therapeutic indications
Kaluma Strong Caplet is a medicated capsule shaped tablet (caplet) formulation containing active ingredients; Paracetamol, Aspirin and Caffeine anhydrous for the temporary relief of pain of headache (including migraine), sinusitis (e.g., sinus congestion, flu and common cold (e.g., nasal congestion), myalgia (muscular ache), arthralgia (joint pain), menstrual discomfort (dysmennorhea), mild to moderate pain, dental pain (toothache), and minor arthritis pain.

4.2 Posology and method of administration
Posology

Adults: 2 caplets after every 6 - 8 hours. Administer with a full glass of water food or milk may minimize gastro-intestinal (GI) upset.

Children above 12 years: Consult a physician.

For pain, do not take for more than 10 days unless directed by a physician.

For fever, do not take for more than 3 days unless directed by a physician.

Method of administration: Oral

4.3 Contraindications

- Not to be taken when on Anticoagulant drugs.

- Not to be taken by those allergic to aspirin or have asthma or recurrent ulcers.

4.4 Special warnings and precautions for use

Before you take Kaluma Strong:

• Do not exceed the stated dose.

• Do not give to children under 12 years of age, as it contains aspirin which may cause Reye-syndrome.

• Care should be taken if given to patients with impaired kidney or liver functions.

• Keep medicines out of reach of children.

• If symptoms persist, consult a doctor.

4.5 Interaction with other medicinal products and other forms of interaction

General Precaution: This combination should not be taken with other NSAIDs, including aspirin and COX-2 inhibitors, due to the potential for increased gastrointestinal and bleeding risks. No significant interaction exists between aspirin and paracetamol when used together.

Aspirin Interactions

- Use with other NSAIDs or corticosteroids may increase the risk of ulcers and gastrointestinal bleeding.
- Combined use with anticoagulants, thrombolytics, or antiplatelets may raise bleeding risk and should be avoided.
- Taking aspirin with SSRIs may increase the risk of gastrointestinal bleeding.
- Co-administration with phenytoin or valproate may increase their blood levels and requires monitoring.
- Using aspirin with diuretics or antihypertensives may reduce their effectiveness and impair kidney function.
- Aspirin may reduce the effect of uricosurics such as probenecid.
- Methotrexate levels may increase with aspirin, which can lead to toxicity.
- Aspirin may enhance the hypoglycemic effect of insulin and sulphonylureas.
- Alcohol use with aspirin may increase the risk of gastrointestinal bleeding.

Paracetamol Interactions

- Use with alcohol, antiepileptics, or rifampicin may increase the risk of liver damage.
- Chloramphenicol levels may rise when taken with paracetamol.

- Zidovudine taken with paracetamol may increase the risk of blood-related side effects.
- Probenecid may reduce paracetamol clearance, requiring dose adjustment.
- Regular use of paracetamol may enhance the effect of oral anticoagulants.
- Slower absorption may occur when combined with agents that delay gastric emptying.
- Faster onset of action may result from combination with agents that speed up gastric emptying.
- Cholestyramine may reduce paracetamol absorption if taken too closely.
- Flucloxacillin with paracetamol may cause metabolic acidosis in certain patients.

Caffeine Interactions

- Combining caffeine with hypnotics or sedatives may reduce their effect.
- Caffeine withdrawal may raise lithium levels, requiring dose adjustment.
- Use of caffeine during disulfiram treatment may worsen withdrawal symptoms.
- Caffeine with ephedrine-like agents or sympathomimetics may increase stimulant effects.
- Theophylline clearance may be reduced when taken with caffeine.
- Some antibiotics and medications may increase caffeine levels by slowing its metabolism.
- Smoking or phenytoin may reduce caffeine's half-life.
- Caffeine may increase clozapine levels and should be monitored during use.

4.6 Pregnancy and Lactation

• Talk to your doctor or pharmacist if you are pregnant or breastfeeding.

• If clinically needed, paracetamol can be used at the lowest effective dose for the shortest possible time during pregnancy.

• During the first and second trimester of pregnancy, acetylsalicylic acid should not be given unless clearly necessary.

• Acetylsalicylic acid is contraindicated during the third trimester of pregnancy.

• Pregnant women are advised to limit caffeine intake to no more than 200 mg per day.

Aspirin and Caffeine appears in breast milk, hence not recommended during breast feeding.

4.7 Effects on ability to drive and use machines

If you notice undesirable effects such as dizziness or drowsiness, you should not drive or use machines. Tell your doctor as soon as possible.

4.8 Undesirable effects
Heartburn and nausea may occur.

This can be avoided by taking medicine after meal or with full glass of water.

Reporting of suspected adverse reactions:
Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

4.9 Overdose
Mild aspirin toxicity may cause dizziness, tinnitus, nausea, vomiting, and confusion at plasma levels of 150–300 mcg/mL, while severe overdose (>300 mcg/mL) can lead to hyperventilation, fever, acidosis, coma, and potentially cardiovascular collapse. Treatment includes activated charcoal, sodium bicarbonate (if >500 mcg/mL), and hemodialysis for severe cases. Paracetamol overdose (>150 mg/kg) can cause delayed but severe liver damage, renal failure, and in extreme cases, death. Early symptoms include nausea, vomiting, and lethargy. Management requires urgent medical attention, with activated charcoal and antidotes like N-acetylcysteine or methionine being most effective within 8–10 hours. Caffeine overdose may present with GI upset, agitation, tremors, insomnia, tachycardia, and arrhythmias. Symptoms are managed by reducing or stopping intake. Significant caffeine overdose from combination products typically co-occurs with serious paracetamol toxicity.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Aspirin has analgesic, antipyretic and anti-inflammatory properties, primarily due to the inhibition of the biosynthesis of prostaglandins and thromboxanes from arachidonic acid by irreversible acetylation of cyclooxygenase (COX) enzymes.

Paracetamol has analgesic and antipyretic properties, but unlike acetylsalicylic acid does not inhibit platelet aggregation.

The addition of caffeine augments the antinociceptive effects of acetylsalicylic acid and paracetamol.

5.2 Pharmacokinetic properties
Aspirin is rapidly absorbed from the GI tract, partially hydrolyzed to salicylic acid, and reaches peak levels in 1–2 hours. It distributes widely, binds to plasma proteins, and is metabolized mainly in the liver. Elimination is through the kidneys and depends on urinary pH. Paracetamol is quickly absorbed, minimally protein-bound at therapeutic doses, and primarily metabolized in the liver to glucuronide and sulfate conjugates, with a half-life of 1–4 hours.

Caffeine is rapidly and completely absorbed, moderately protein-bound, extensively metabolized in the liver, and eliminated with a variable half-life averaging around 4.9 hours.

5.3 Preclinical safety data
Not applicable

6. Pharmaceutical Particulars
6.1 List of Excipients
Maize Starch BP,

Gelatin BP,

Propyl Hydroxy Benzoate BP,

Colloidal Silicon Dioxide USP/NF,

Croscarmellose Sodium USP/NF,

Stearic Acid BP,

Purified Talc BP,

Purified Water BP

6.2 Incompatibilities
Not applicable.

6.3 Shelf-Life
30 months (2.5 Years)

6.4 Special Precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and Content of container

50 strips containing 2 tablets in a carton and 10 strips containing 2 tablets in a carton.

6.6 Special precautions for disposal and other handling
No special requirement

7. Marketing Authorization Holder
SHALINA HEALTHCARE KENYA LIMITED,

Shalina House, Baba Dogo Road,

P.O Box 39597 – 00623 Nairobi, Kenya.

Manufacturing Site Address:

Bal Pharma Limited, 21 & 22, Bommasandra Industrial Area, Bangalore-560 099, India

8. Marketing Authorization Number

H2008/18589/174/R1

9. Date of first authorization/renewal of the authorization

2026 June 22

10. Date of revision of the text

2026 June 22