SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Shalina APC Tablets (Aspirin, Paracetamol and Caffeine Tablets)

STRENGTH
Each uncoated Tablet contains:
Paracetamol BP……250mg
Aspirin BP……150mg
Caffeine (Anhydrous) BP……30mg

PHARMACEUTICAL FORM
Tablets (Oral)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Tablets (Oral)
Pink coloured, circular flat faced beveled edge uncoated tablet with cross line on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Shalina APC is a combination of Aspirin, Paracetamol and Caffeine. It has anti-inflammatory and antipyretic properties. Caffeine stimulates the nervous system, acts on the stomach muscle and the myocardium. It has some diuretic effect. It is used in the symptomatic management of pain and fever. Shalina APC acts mainly by inhibiting prostaglandin synthesis. It is used for Mild to moderate pain, pyrexia and inflammation in rheumatic diseases and other musculoskeletal disorders.

4.2 Posology and method of administration
• Adults: 1-2 tablets three times a day after meals. Do not exceed 8 tablets in a day. Do not give to children under 12 years of age.
• Children above 12 yrs: Consult a doctor.

4.3 Contraindications
• with known hypersensitivity (e.g., bronchospasm, rhinitis, urticaria) to acetylsalicylic acid or other salicylates, paracetamol, caffeine or to any other components of the product.
• with a history of hypersensitivity reactions (e.g., asthma, rhinitis, urticaria) induced by the administration of salicylates, or substances with similar actions, notably non-steroidal anti-inflammatory drugs.
• with active or a history of peptic ulcers.
• with haemorrhagic diathesis such as haemophilia.
• with severe renal failure.
• with severe hepatic failure.
• with severe cardiac failure.
• with severe cardiovascular disease

• with severe uncontrolled hypertension.
• in the third trimester of pregnancy (see section 4.6).
• who are breastfeeding.
• receiving doses of methotrexate at 15mg/week or greater (see section 4.5)

4.4 Special warnings and precautions for use

Caution should be exercised in the following cases:
• hypersensitivity to analgesics / anti-inflammatory agents / anti-rheumatics and in the presence of other allergies,
• with a history of gastrointestinal disorders,
• with concomitant treatment with anticoagulants (e.g., coumarin derivatives or heparin) (see section 4.5),
• patients with impaired renal function or patients with impaired cardiovascular circulation (e.g., renal vascular disease, congestive heart failure, volume depletion, major surgery, sepsis or major haemorrhagic events), since acetylsalicylic acid and paracetamol may further increase the risk of renal impairment and acute renal failure.Dosing adjustment may be required, in particular in case of severe renal insufficiency (creatinine clearance < 10 mL/min) where the benefit/risk ratio of paracetamol use should be evaluated and dosing adjustment and continuous monitoring must be ensured.
• patients with impaired hepatic function due to disease or infections affecting the liver such as viral hepatitis, or hepatic insufficiency (Child-Pugh < 9). The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. An elevation of serum alanine aminotransferase (ALT) may occur during the administration of therapeutic doses of paracetamol.
• patients with conditions that increase the hepatic oxidative stress and decrease the hepatic glutathione reserve such as a variety of concomitant drugs (see section 4.5), alcoholism or diabetes mellitus, as it may place the patient at increased risk of hepatic toxicity to paracetamol at therapeutic doses.
• patients suffering from Gilbert syndrome as it may lead to more pronounced hyperbilirubinemia and clinical symptoms thereof such as jaundice.
• patients with hyperthyroidism.
• in the first or second trimester of pregnancy (see section 4.6)

Acetylsalicylic acid may precipitate bronchospasm and induce asthma attacks or other hypersensitivity reactions. Risk factors are pre-existing asthma, hay fever, nasal polyps, or chronic respiratory disease. This also applies to patients exhibiting allergic reactions (e.g., cutaneous reactions, itching, urticaria) to other substances.

Rare cases of acute myocardial ischemia with or without myocardial infarction as part of a hypersensitivity reaction (Kounis syndrome) have been reported in patients treated with acetylsalicylic acid. In the event of confirmed Kounis syndrome due to acetylsalicylic acid, Alka-Seltzer XS should be discontinued immediately.

Due to its inhibitory effect on platelet aggregation which persists for several days after administration, acetylsalicylic acid may lead to an increased bleeding tendency during and after surgical operations (including minor surgeries, e.g., dental extractions).

At low doses, acetylsalicylic acid reduces the excretion of uric acid. This can possibly trigger gout attacks in predisposed patients.

There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which affects the brain and liver, and can be fatal. For this reason, aspirin should not be given to children aged under 16 years unless specifically indicated (e.g., Kawasaki's disease).

In patients suffering from severe glucose-6-phosphate dehydrogenase (G6PD) deficiency, acetylsalicylic acid and paracetamol may induce haemolysis or haemolytic anaemia. Factors that may increase the risk of haemolysis are high dosage, fever, or acute infections, for example.
SHALINA APC Tablets contain paracetamol, and so other paracetamol-containing preparations should be avoided. The maximum dose of paracetamol for adults is 4g daily.
Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g., chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

Do not exceed the recommended dose. If symptoms persist, consult your doctor. Keep out of the reach of children

4.5 Interaction with other medicinal products and other forms of interaction

Acetylsalicylic acid:
Contraindicated Interactions:
Methotrexate used at doses of 15 mg/week or more:
Increased haematological toxicity of methotrexate (decreased renal clearance of meth-otrexate by anti-inflammatory agents in general and displacement of methotrexate from its plasma protein binding by salicylates) (see section 4.3 Contraindications).
Combinations requiring precautions for use:
Methotrexate, used at doses of less than 15 mg/week:
Increased haematological toxicity of methotrexate (decreased renal clearance of methotrexate by anti-inflammatory agents in general and displacement of methotrexate from its plasma protein binding by salicylates).

Anticoagulants, thrombolytics/other inhibitors of platelet aggregation/haemostasis:
Increased risk of bleeding.

Other non-steroidal anti-inflammatory drugs with salicylates at higher doses:
Increased risk of ulcers and gastrointestinal bleeding due to synergistic effect.

Selective Serotonin Re-uptake Inhibitors (SSRIs):
Increased risk of upper gastrointestinal bleeding due to possibly synergistic effect.

Digoxin:
Plasma concentrations of digoxin are increased due to a decrease in renal excretion.
Antidiabetics, e.g., insulin, sulphonylureas:

Increased hypoglycaemic effect by high doses of acetylsalicylic acid via hypoglycaemic action of acetylsalicylic acid and displacement of sulphonylurea from its plasma protein binding.

Diuretics in combination with acetylsalicylic acid at higher doses:
Decreased glomerular filtration via decreased renal prostaglandin synthesis.

Systemic glucocorticoids, except hydrocortisone used as replacement therapy in Addison's disease:
Decreased blood salicylate levels during corticosteroid treatment and risk of salicy-late overdose after this treatment is stopped via increased elimination of salicylates by corticosteroids.

Corticosteroids:
Potentiate the risk of gastro-intestinal bleeding during concomitant therapy with corticosteroids.

Angiotensin converting enzyme inhibitors (ACE) in combination with acetyl-salicylic acid at higher doses:
Decreased glomerular filtration via inhibition of vasodilatory prostaglandins. Furthermore, decreased antihypertensive effect.

Valproic acid and Phenytoin:
Increased toxicity of valproic acid due to displacement from protein binding sites. Phenytoin is also extensively bound to plasma proteins therefore it can be displaced by acetylsalicylic acid from plasma binding.

Alcohol:
Increased damage to gastro-intestinal mucosa and prolonged bleeding time due to additive effects of acetylsalicylic acid and alcohol.

Uricosurics such as benzbromarone, probenecid:
Decreased uricosuric effect (competition of renal tubular uric acid elimination).

Caffeine
Caffeine antagonizes the sedating effects of many substances such as certain anti-seizure medicines (e.g., Phenobarbital, carbamazepine, valproate), first generation antihistamines (e.g., chlorpheniramine) etc.

Caffeine acts synergistically with the tachycardiac effects of, for example, sympathomimetics, thyroxin, etc.

In case of substances having a broad spectrum of action (e.g., benzodiazepines) the interactions can vary individually and may be unpredictable. These interactions may increase with intake of higher doses of caffeine per day.

Cytochrome P450 1A2 (CYP1A2) is known to be the major enzyme involved in the metabolism of caffeine. Therefore, caffeine has the potential to interact with drugs that are substrates for CYP1A2.
Caffeine reduces the excretion of theophylline.

Oral contraceptives, cimetidine, and disulfiram slow down degradation of caffeine in the liver; barbiturates and smoking accelerate it.

The simultaneous use of gyrase inhibitors of the quinolonecarboxylic acid-type can delay the elimination of caffeine and its metabolite paraxanthine.

Paracetamol
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine or propantheline.
Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4).
Concomitant use of drugs which cause enzyme induction in the liver, e.g., certain hypnotics and antiepileptics (glutethimide, phenobarbital, phenytoin, carbamazepine etc.) or rifampicin may lead to liver damage even after paracetamol doses which would otherwise be harmless.
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding and elevated international normalized ratio (INR). This is due to the interference of paracetamol (or its metabolites) with enzymes involved in vitamin K-dependent coagulation factor synthesis.

4.6 Pregnancy and lactation
Pregnancy
***Acetylsalicylic acid*:**
Doses of 500 mg/day and above:
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.
During the first and second trimester of pregnancy, acetylsalicylic acid should not be given unless clearly necessary. If acetylsalicylic acid is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
• cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
• renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;
the mother and the neonate, at the end of pregnancy, to:
• possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
• inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, acetylsalicylic acid at doses of 100 mg/day and higher is contraindicated during the third trimester of pregnancy.

Caffeine
Caffeine studies have not identified an association between congenital malformations and maternal caffeine consumption in humans.

Paracetamol:
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, patients should follow the advice of their doctor regarding its use.

Breastfeeding
Acetylsalicylic acid:
Breastfeeding is contraindicated at high doses because of the theoretical risk of affecting clotting mechanisms.
The intake of acetylsalicylic acid by breastfeeding patients should be avoided as there is a risk of Reye's syndrome. Regular use of high doses could impair platelet function and produce hypoprothrombinaemia in the infant if neonatal vitamin K stores are low.

Caffeine:
Caffeine and its metabolites pass into breast milk.
Breast-feeding women should limit total caffeine intake to a maximum of 200 mg per day (including caffeine from medicinal products, food and beverages). Excessive caffeine intake may cause restlessness/irritability in the breast-fed infant.

Paracetamol:
Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data on paracetamol does not contraindicate it for breastfeeding.

Fertility
There is some evidence that drugs which inhibit cyclo-oxygenase / prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment.

4.7 Effects on ability to drive and use machines
Not Applicable.

4.8 Undesirable effects
Acetylsalicylic acid:
The listed adverse drug reactions are based on spontaneous reports, thus an organization according to CIOMS III categories of frequency is not possible.

Blood and lymphatic system disorders
Increased risk of bleeding (due to effect on platelet aggregation). In the context of bleeding: haemorrhagic anaemia, iron deficiency anaemia with the respective laboratory and clinical signs and symptoms. In the context of glucose-6-phosphate dehydrogenase (G6PD) deficiency: haemolysis, haemolytic anaemia
Immune system disorders

Hypersensitivity, drug hypersensitivity, allergic edema and angioedema, anaphylactic reaction, anaphylactic shock with respective laboratory and clinical manifestations

Nervous system disorders
Cerebral and intracranial haemorrhage, dizziness
Ear and labyrinth disorders
Tinnitus

Cardiac disorders
In the context of severe allergic reactions: cardio-respiratory distress
Kounis syndrome (acute myocardial ischemia with or without myocardial infarction as part of a hypersensitivity reaction, see section 4.4 “Special warnings and precautions for use”) with frequency not known.

Vascular disorders
Haemorrhage, operative haemorrhage, haematoma, muscle haemorrhage
Respiratory, thoracic and mediastinal disorder
Epistaxis, analgesic asthma syndrome, rhinitis, nasal congestion, bronchospasm

Gastrointestinal disorders
Dyspepsia, gastrointestinal pain, abdominal pain, gingival bleeding, gastrointestinal inflammation, gastrointestinal ulcer, gastrointestinal haemorrhage, gastrointestinal ulcer perforation with the respective laboratory and clinical signs and symptoms, nausea, diarrhoea, vomiting

Hepatobiliary disorders
Liver disorder, transaminases increased
Skin and subcutaneous tissue disorders
Rash, urticaria, pruritus, severe skin reactions
Renal and urinary disorders
Impaired renal function
Injury, poisoning and procedural complications
See overdose section

Caffeine
Cardiac disorders
Caffeine in high doses can cause cardiac effects, such as palpitations, flushing, arrhythmias, hypertension, and tachycardia.

Nervous system disorders
The caffeine component can lead to central nervous system effects, such as headache, insomnia, and inner restlessness.

Paracetamol:
The listed adverse drug reactions are based on spontaneous reports, thus an organization according to CIOMS III categories of frequency is not possible.
Blood and lymphatic system disorders:
There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

Hepatobiliary disorders:

Hepatic dysfunction.
Immune system disorders:
Anaphylaxis.
Cutaneous hypersensitivity reactions including, among others, skin rashes and angioedema. Very rare cases of serious skin reactions have been reported.

Respiratory, thoracic and mediastinal disorders:
Bronchospasm.
There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

Skin and subcutaneous tissue disorders:
Very rare cases of serious skin reactions have been reported.

Reporting of suspected adverse reactions:
Healthcare professionals are requested to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose
Paracetamol
Liver damage is possible in adults who have taken 10g or more of paracetamol.
Symptoms
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.
Management
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention and any patient who had ingested around 7.5g or more of paracetamol in the preceding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose, may be required. General supportive measures must be available.

Acetylsalicylic acid
Salicylate poisoning is usually associated with plasma concentrations >350 mg/L (2.5 mmol/L). Most adult deaths occur in patients whose concentrations exceed 700 mg/L (5.1 mmol/L). Single doses less than 100 mg/kg are unlikely to cause serious poisoning.
Symptoms
Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.
A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis

with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.
Uncommon features include hematemesis, hyperpyrexia, hypoglycemia, hypokalemia, thrombocytopenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.
Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

Management

Give activated charcoal if an adult presents within one hour of ingestion of more than 250 mg/kg. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinization, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.
Hemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700 mg/L (5.1 mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

Caffeine

In the event of caffeine overdose, symptomatic treatment of adverse events (e.g., cardiac) is recommended.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Salicylic acid and derivatives, combinations excluding psycholeptics (Analgesic, Anti-inflammatory) . ATC Code: N02BA51.

5.1 Pharmacodynamic properties

Shalina APC is a combination of Aspirin, Paracetamol and Caffeine. It has anti-inflammatory and antipyretic properties. Caffeine stimulates the nervous system, acts on the stomach muscle and the myocardium. It has some diuretic effect. It is used in the symptomatic management of pain and fever. Shalina APC acts mainly by inhibiting prostaglandin synthesis.

5.2 Pharmacokinetic properties

Aspirin absorption occurs in the stomach in non-ionized form. Acetylsalicylates and Salicylates are rapidly absorbed from the gastrointestinal tract. Hydrolysis of salicylic acid takes place rapidly in the intestine and in the circulation. Salicylates are extensively bound to plasma proteins while aspirin is bound to a lesser degree. Aspirin is rapidly distributed to all body tissues:
appear in milk and cross the placenta. Aspirin is mainly eliminated by hepatic metabolism; the metabolites include salicylic acid, salicyl phenolic glucuronide, salicylic acyl glucuronide, gentisic acid and genstisuric acid. Excretion of aspirin is affected by pH of the urine, increasing as the pH rises and being maximum at pH 7.5 and above. Aspirin is excreted as salicylic acid and glucuronide-conjugates
as well as salicyluric and gentisic acids.
Paracetamol is readily absorbed from the gastrointestinal tract with a peak plasma concentration occurring about 10 to 60 minutes after oral administration. It is

distributed into most body tissues. It crosses the placenta and is present in breast milk. The administration half-life of the drug varies from about 1 to 3 hours. It is metabolized predominantly in the liver and excreted in the
urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as uncharged paracetamol.
Caffeine is also readily absorbed in gastrointestinal tract; the absorption may be erratic, peak plasma concentrations of 1.5 to 1.8 mcg per ml were found 50 to 70 minutes after a dose of 100 mg of caffeine.

5.3 Preclinical safety data
None

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Maize starch BP
Pregelatinized Starch BP
Sodium Starch Glycolate BP
Gelatin BP
Methyl Hydroxybenzoate BP
Erythrosine Lake Colour IH
Colloidal Silicon Dioxide BP

6.2 Incompatibilities
None.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store in a cool & dry place below 30°C. Protect from direct sunlight.

6.5 Nature and contents of container
10 strips containing 10 tablets in a packet.

6.6 Special precautions for disposal and other handling
None.

7. MARKETING AUTHORIZATION HOLDER
Manufactured by:
DINLAS PHARMA (AFRICA) LIMITED
Plot No. LR 7149/121, Mombasa Road, Syokimau,
P.O. Box 22661-00505, Nairobi, Kenya

Marketed by:
Shalina Healthcare Kenya Limited
Shalina House, Baba Dogo Road,
P.O Box 39597 – 00623 Nairobi, Kenya.

8. MARKETING AUTHORIZATION NUMBER
2008/19150/298

9. DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION
Date of first authorization: 13 February 2008
Date of latest renewal: Renewal application

10. DATE OF REVISION OF TEXT
22 July 2026