SUMMARY PRODUCT CHARACTERISTICS

HEDEX TABLETS

1.0 NAME OF THE MEDICINAL PRODUCT:

1.1 Proprietary Name: HEDEX Tablets

1.2 International Non-Proprietary Name (INN): Aspirin, Paracetamol and Caffeine Tablets.

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each tablet contains – Aspirin 400mg, Paracetamol 200mg and Caffeine Anhydrous 50mg

3.0 PHARMACEUTICAL FORM:

3.1 Pharmaceutical dosage form: Tablets

3.2 Description: White caplet shaped tablets engraved "HEDEX" on both sides.

4.0 CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Hedex Tablet is a mild analgesic and antipyretic formulated to give extra relief from pain. Hedex Tablets recommended for treatment of most painful and febrile conditions like headaches, including migraine, backache, toothache, rheumatic pain and dysmenorrhea, and the relief of the symptoms of colds, flu and sore throat.

4.2 Posology and method of administration: Oral use. As directed by the physician OR

Adults (including elderly), and children aged 16 yrs. and over: 1 or 2 tablets every 3 hours up to 4 times daily. The dose should not be repeated more frequently than every 4 hours. Do not exceed 8 tablets in 24 hours. Not recommended for children under 16 years.

4.3 Contraindications: Hypersensitivity to salicylic acid compounds or prostaglandin synthetase inhibitors (e.g. certain asthma patients who may suffer an attack or faint and certain patients who may suffer from bronchospasm, rhinitis and urticaria), Paracetamol, caffeine or any of the other ingredients.

4.4 Special warnings and precautions for use: Children below 16yrs should not use this medication for chicken fox or flu symptoms before a doctor is consulted about Reyes syndrome. Do not use for pain for more than 5 days or for fever for more than 3 days. Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. The hazard of overdose is greater in those with noncirrhotic alcoholic liver disease. Excessive intake of caffeine (coffee, tea and some canned drinks) should be avoided while taking this product. Do not exceed stated dose.

Patients are advised not to take other paracetamol containing products concurrently. 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: The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with risk of bleeding; occasional doses have no significant effect. Concomitant use of aspirin with other drugs that alter haemostasis (i.e. anticoagulants such as warfarin, thrombolytic and antiplatelet agents, anti-inflammatory drugs and selective serotonin reuptake inhibitors) is not recommended, unless strictly indicated, because they may enhance the risk of haemorrhage

4.6 Fertility, pregnancy and lactation: Paracetamol-caffeine is not recommended for use during pregnancy due to the possible increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption. Caffeine in breast may potentially have a stimulating effect on breast fed infants.
Due to the caffeine content of this product it should not be used if you are pregnant or breast feeding. Aspirin should be avoided in late pregnancy and generally during breast feeding.

4.7 Effects on ability to drive and use machines: None

4.8 Undesirable effects: ***Body system:*** Blood and lymphatic system disorders; Thrombocytopenia and agranulocytosis. ***Immune system disorders:*** Anaphylaxis, Cutaneous hypersensitivity reactions including skin rashes, angioedema and Steven Johnson syndrome/toxic epidermal necrosis. ***Respiratory, thoracic and mediastinal disorders:*** Bronchospasm (there has been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs. ***Hepatobiliary disorders***: hepatic dysfunction

Caffeine: Central nervous system; nervousness and dizziness.
When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine related adverse effects as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.

4.9 Overdose: Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has the below noted risk factors. ***Risk factors:*** a) If the patient: is on long term treatment carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's wort or other drugs that induce liver enzymes. Or b) regularly consumes ethanol in excess of recommended amounts. Or C) is likely to be glutathione deplete e.g disorders, cystic fibrosis, HIV infection, starvation,

cachexia. ***Symptoms:*** Symptoms of paracetamol over dosage in the first 24hours are pallor, nausea, vomiting anorexia and abdominal pain. Liver damage may become apparent 12 to 48hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycemia, cerebral oedema and death. Acute renal failure with tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatic 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. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, See BNF overdose section. Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion.(earlier concentrations are unreliable).Treatment with N-acetylcysteine may be used upto 24 hours after ingestion of paracetamol. However the maximum protective effect is obtained upto 8 hours post ingestion. Effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If the vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 hour from ingestion should be discussed with NIPS or liver unit.

Caffeine: ***Symptoms:*** overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia, or cardia arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors, and convulsions). It must be noted that for clinically significant symptoms of caffeine overdose to occur with HEDEX the amount ingested would be associated with serious paracetamol related toxicity. ***Management:*** Patients should receive general supportive care (e.g hydration and maintenance of vital signs). The administration of activated charcoal may be beneficial when performed within one hour of overdose, but can be considered for upto four hours after the over dose. The CNS effects of overdose may be treated intravenous sedatives. **Aspirin:** Although considerable inter-individual variations are involved, it can be considered that the toxic dose is about 200mg/kg in adults and 100mg/kg in children. The lethal dose of acetylsalicylic acid is 25-30 grams. Salicylate poisoning is usually associated with plasma concentrations >300mg/L (2.5 mmol/L). Plasma concentrations above 500mg/l in adults and 300mg/l in children generally cause severe toxicity. 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. **Management:** If a toxic dose has been ingested, hospital admission is required. In the event of moderate intoxication, inducing the patient to vomit should be attempted. If this fails, gastric lavage may be attempted during the first hour after ingestion of a substantial amount of the

medicine. **Summary:** Treatment of overdose requires assessment of plasma paracetamol levels for antidote treatment, with signs and symptoms of caffeine toxicity being managed symptomatically.

5.0 PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamics properties:

Pharmacotherapeutic group and ATC code: NO2B E51.

The combination of Aspirin Paracetamol and caffeine is a well established combination.

5.2 Pharmacokinetic properties: After oral administration, acetylsalicylic acid is rapidly absorbed from the gastrointestinal tract. However, a significant portion of the dosage is already hydrolysed to salicylic acid in the intestinal wall during the absorption process. Paracetamol is rapidly and almost completely absorbed from the gastro intestinal tract. It is relatively uniformly distributed throughout most body fluids and exhibits variable protein binding. Excretion is almost exclusively renal, in the form of conjugated metabolites. Caffeine is absorbed readily after oral administration. Maximal plasma concentrations are achieved within one hour and the plasma half-life is about 3.5 hours.65%-80%of administered caffeine is excreted in urine as 1-methyuric and 1-methlxamine.

5.3 Preclinical safety data: There are no pre-clinical data of relevance to prescriber which are additional to that already included in other sections of the SPC.

6.0 PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients: Maize Starch, Povidone, pre-gelatinized starch, Purified Talc, stearic acid, Potassium Sorbate.

6.2 Incompatibilities: None

6.3 Shelf life: 24 months.

6.4 Special precautions for storage: Store in a cool dry place below 30˚C. Protect from light.

6.5 Nature and contents of container: Blister pack of 10x10 tablets or 2x10 tablets along with a leaflet.

6.6 Special precautions for disposal: None

7.0 MANUFACTURED BY:

GLAXOSMITHKLINE PHARMACEUTICAL KENYA LIMITED
Address: Likoni Road, Nairobi
Country: Kenya
Telephone:+254206933
200/6534 241 Website:
www.gsk.com

8.0 Date of issue: May, 2021