Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
MARA MOJA Advance Tablets

2. Qualitative and quantitative composition
Each tablet contains: Paracetamol 500mg and Caffeine 65mg

For the full list of excipients, see section 6.1

3. Pharmaceutical form
Tablet
White to off-white caplet shaped tablets, plain on one side and a break line on the other.

4. Clinical particulars

4.1 Therapeutic indications
MARA MOJA Advance is a mild analgesic and antipyretic formulated to give extra relief from pain. MARA MOJA Advance is 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

Posology

Adults (including the elderly) and children aged 16 years and over:
2 tablets up to four times daily. Do not exceed 8 tablets in 24 hours.

Children aged 12 – 15 years: 1 tablet up to four times daily. Do not exceed 4 tablets in 24 hours.

Not recommended for children under 12 years of age.

Minimum dosing interval: 4 hours.
The lowest dose necessary to achieve efficacy should be used.

Should not be used with other paracetamol-containing products.

Renal Impairment
Patients who have been diagnosed with renal impairment must seek medical advice before taking this medication. The restrictions related to the use of paracetamol and caffeine products in patients with renal impairment are primarily a consequence of the paracetamol content of the drug.

Hepatic Impairment
Patients who have been diagnosed with liver impairment must seek medical advice before taking this medication. The restrictions related to the use of paracetamol and caffeine products in patients with hepatic impairment are primarily a consequence of the paracetamol content of the drug.

The maximum daily dose of paracetamol should not exceed 60mg/kg/day (up to a maximum of 2g per day) in the following situations, unless directed by a physician:

- Weight less than 50kg
- Chronic alcoholism
- Dehydration
- Chronic malnutrition

Method of administration

Oral use.

4.3 Contraindications

Known hypersensitivity to paracetamol, caffeine or any of the other ingredients.

4.4 Special warnings and precautions for use

Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

Cases of paracetamol induced hepatotoxicity, including fatal cases, have been reported in patients taking paracetamol at doses within the therapeutic range. These cases were reported in patients with one or more risk factors for hepatotoxicity including low body weight (<50 Kg), renal and hepatic impairment, chronic alcoholism, concomitant intake of hepatotoxic drugs, sepsis and in acute and chronic malnutrition (low reserves of hepatic glutathione). Paracetamol should be administered with caution to patients with these risk factors.

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.

Caution is also advised in patients on concomitant treatment with drugs that induce hepatic enzymes and in conditions which may predispose to glutathione deficiency (see sections 4.2 and 4.9). In patients with glutathione depleted states such as sepsis; the use of paracetamol may increase the risk of metabolic acidosis.

Doses of paracetamol should be reviewed at clinically appropriate intervals and patients should be monitored for emergence of new risk factors for hepatoxicity which may warrant dosage adjustment.

Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

Excessive intake of caffeine (e.g. coffee and some canned drinks) should be avoided while taking this product.

Prolonged use except under medical supervision may be harmful. In general, medicinal products containing paracetamol should be taken for only a few days without the advice of a doctor or dentist and not at high doses.

Do not exceed the stated dose. Take only when necessary. If high fever or signs of secondary infection occur or if symptoms persist for longer than 3 days, a physician should be consulted.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol

Paracetamol may increase the elimination half-life of chloramphenicol. The absorption of paracetamol may be increased by metoclopramide and decreased by colestyramine. Oral contraceptives may increase the rate of clearance of paracetamol.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

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)

Caffeine

Caffeine can increase the elimination of lithium from the body. Concomitant use is therefore not recommended.

4.6 Pregnancy and Lactation

Pregnancy

Paracetamol
A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results.

Caffeine
Paracetamol-caffeine is not recommended for use during pregnancy due to the possible increased risk of spontaneous abortion associated with caffeine consumption.

Lactation

Paracetamol and caffeine are excreted in breast milk. Not recommended for use during breastfeeding.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by System Organ Class and frequency.

Frequencies are defined as: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data).

Adverse event frequencies have been estimated from spontaneous reports received through post marketing data.

Substance	Body System	Undesirable Effect(s)	Frequency
Paracetamol	Blood and lymphatic system disorders	Thrombocytopaenia	Very rare
	Immune system disorders	Anaphylaxis, Cutaneous hypersensitivity reactions, Angioedema, Stevens-Johnson syndrome, Toxic epidermal necrolysis	Very rare
		Very rare cases of serious skin reactions have been reported	Very rare
	Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
	Hepatobiliary disorders	Hepatic dysfunction	Very rare
Caffeine	Central nervous system	Nervousness, Dizziness	Unknown
	Cardiac disorders	Palpitation	Not known
	Psychiatric disorders	Insomnia, Restlessness, Anxiety, Irritability	Not known
	Gastrointestinal disorders	Gastrointestinal disturbances	Not known

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 such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.

Reporting of suspected adverse reactions: 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

Paracetamol

Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity. There is a risk of poisoning with paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdosing may be fatal in these cases.

Symptoms generally appear within the first 24 hours and may comprise: nausea, vomiting, anorexia, pallor, and abdominal pain, or patients may be asymptomatic.

Overdose of paracetamol in a single administration in adults or in children can cause liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may lead to coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration. Liver damage is likely in adults who have taken more than the recommended amounts of paracetamol. It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Some patients may be at increased risk of liver damage from paracetamol toxicity. Risk Factors include: If the patient;

- Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- Regularly consumes ethanol in excess of recommended amounts
- Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

Emergency Procedure:
Immediate transfer to hospital.
Blood sampling to determine initial paracetamol plasma concentration.
In the case of a single acute overdose, paracetamol
plasma concentration should be measured 4 hours post ingestion.
Administration of activated charcoal should be considered if
>150mg/kg paracetamol has been taken within 1 hour.
The antidote N-acetylcysteine, should be administered as soon as possible in accordance with National treatment guidelines.
Symptomatic treatment should be implemented.

Caffeine
Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac 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 this product, the amount ingested would be associated with serious paracetamol-related liver toxicity. No specific antidote is available, but supportive measures such as beta adrenceptor antagonists to reverse the cardiotoxic effects may be used.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: N02B E51 - Paracetamol combinations

The combination of paracetamol and caffeine is a well established analgesic combination.

Paracetamol is a p-aminophenol derivative that possesses analgesic and antipyretic activity but lacks anti-inflammatory effects. It produces analgesia primarily through the central inhibition of prostaglandin synthesis.

Caffeine is a central nervous system stimulant that increases alertness and may cause restlessness and agitation. It relaxes smooth muscle, stimulates cardiac muscle contraction, and can enhance athletic performance. Additionally, caffeine promotes gastric acid secretion, increases gastrointestinal motility, and acts as a mild diuretic. It is commonly combined with analgesics and ergot alkaloids in the treatment of migraines and headaches.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract and is relatively uniformly distributed throughout body fluids, with variable protein binding. It is excreted almost exclusively by the kidneys in the form of conjugated metabolites.

Caffeine is also rapidly absorbed after oral administration, reaching maximum plasma concentrations within one hour. It has a plasma half-life of approximately 3.5 hours, and between 65% and 80% of the administered dose is excreted in the urine as 1-methyluric acid and 1-methylxanthine.

5.3 Preclinical safety data

Preclinical safety data on paracetamol in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product and which have not been mentioned elsewhere in this summary.

6. Pharmaceutical Particulars

6.1 List of Excipients

Microcrystalline Cellulose
Maize Starch
Povidone
Purified Talc
Magnesium Stearate
Colloidal Anhydrous Silica
Croscarmellose Sodium

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 light.

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

6.6 Special precautions for disposal and other handling
Do not throw away unused medicines. Ask pharmacist or medical facility about proper disposal. These measures help protect the environment

7. Marketing Authorization Holder
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8. Marketing Authorization Number
CTD9559

9. Date of first authorization/renewal of the authorization
18/04/2024

10. Date of revision of the text
05/06/2025