SUMMARY OF PRODUCT CHARACTERISTICS.

1. Name of the medicinal product

Curamol 500mg Tablets.

2. Qualitative and quantitative composition

Each tablet contains: Paracetamol 500mg.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet for oral use.

White coloured tablets, scored and embossed P/500 on one side and plain on the other side.

4.0 Clinical particulars

4.1 Therapeutic indications

Paracetamol has an analgesic and antipyretic properties and weak anti-inflammatory activity. Paracetamol is recommended for treatment of painful and febrile conditions, for example headache, toothache, sore throat, colds, influenza and rheumatic pain.

4.2 Posology and method of administration

Method of administration: Oral route

Dosage & Administration.

Adults and children over age 12: - 325 to 650 mg orally to be taken every four to six hours. Maximum dose should not exceed 4g daily. Dosage for long-term therapy should not exceed 2.6g daily.

Children under age 12: 1.5g/m2 body weight daily in divided doses or as shown below.

Children age 9 to 12 years: 1 tablet (10 ml of the syrup), 2 tablets junior every 4 to 6 hours. Children age 5 to 8 years: 7.5 ml of the syrup, 1½ tablets Junior every 4 to 6 hours.

Children age 1 to 4 years: 5 ml, 1 tablet Junior every 4 to 6 hours. Children under 1 year: 2.5 ml every 4 to 6 hour or as directed by a Physician.

4.3 Contraindications

Paracetamol is contraindicated in-patients with known hypersensitivity to this compound. Administer the drug cautiously to patients with anaemia, hepatic or renal disease because it has been known to induce these disorders; and to patients with a history of gastrointestinal disease, increased risk of gastrointestinal bleeding, or decreased renal function. Paracetamol may mask the signs and symptoms of acute infection (fever, myalgia, and erythema); patients with high infection risk (such as those with diabetes) should be carefully evaluated.

4.4 Special warnings and precautions for use

Has no significant anti-inflammatory effect. In spite of this, studies have shown substantial benefit in-patients with osteoarthritis of the knee. Therapeutic benefits may stem from the drug's analgesic effects. Many nonprescription products contain paracetamol. Be aware of this when calculating total daily dose. Patients unable to tolerate aspirin may be able to tolerate paracetamol tablet. Use this medication cautiously in the presence of alcoholism, hepatic disease, viral infection, renal function impairment, or cardiovascular disease. Monitor vital signs, especially temperature, to evaluate drug's effectiveness. Assess patient's level of pain and response before and after administration.

4.5 Interaction with other medicinal products and other forms of interaction.

Concomitant use of Paracetamol may potentiate the effects of anticoagulants and thrombolytic drugs, but this effect appears to be clinically insignificant. Combined caffeine and Paracetamol may enhance the therapeutic effect of Paracetamol. Concomitant use of phenothiazines and Paracetamol in large doses may result in hypothermia.

4.6 Fertility, pregnancy and lactation.

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is

excreted in breast milk but not in clinically significant quantities. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines.

None known.

4.8 Undesirable effects.

Central Nervous System: mental changes, stupor, confusion, agitation (with toxic doses), weakness rash, urticaria, itching, unusual bruising, erythema.

Eye, Ear, Nose & Throat: unexplained sore throat, nausea, vomiting, diarrhea, abdominal cramps, abdominal pain, loss of appetite. Bloody or cloudy urine, difficult or painful urination, sudden decreases in amount of urine. Unusual bleeding, tiredness or weakness, hemolytic anaemia, neutropenia, leukopenia, pancytopnia, thrombocytopenia, methemoglobinemia. Severe liver damage (toxic doses). Others: hypoglycemia, jaundice, unexplained fever.

4.9 Overdose

In acute overdose, plasma levels of 300 mcg/ml 4 hours post-administration are associated with hepatotoxicity, clinical manifestations of overdose include cyanosis, anemia, jaundice, skin eruptions, fever, emesis, central Nervous system stimulation, delirium, methemoglobinemia progressing to depression, coma, vascular collapse, convulsions, and death. Paracetamol poisoning develops in stages. Stage 1 (12 to 24 hours after ingestion): nausea, vomiting, diaphoresis, anorexia.

Stage 2 (24 to 48 hours after ingestion): clinically improved but elevated liver function tests. Stage 3 (72 to 96 hours after ingestion): peak hepatotoxicity. Stage 4 (7 to 8 days after ingestion): recovery To treat overdose of paracetamol tablet, hemodialysis may be helpful to remove from the body. Monitor laboratory parameters and vital signs closely. Cimetidine has been used investigationally to block metabolism to toxic intermediates. Provide symptomatic and supportive measures (respiratory support, correction of fluid and electrolyte imbalances). Determine plasma levels atleast 4 hours after overdose. If plasma levels indicate hepatotoxicity, perform liver function tests every 24 hours for atleast 96 hours.

5. Pharmacological properties.

5.1 Pharmacodynamic properties.

***Pharmacotherapeutic group*:** Other analgesics and antipyretics, Anilides.

ATC code: N02B E01.

Paracetamol is a para-aminophenol derivative non-narcotic analgesic, antipyretic agent. It inhibits the synthesis of prostaglandins which are associated with the development of pain, producing analgesia. In fever prostaglandins act within the hypothalamus to produce the resultant elevation of body temperature by processes that appear to be mediated by cyclic AMP. Paracetamol suppresses this response by inhibiting the synthesis of PGE.

5.2 Pharmacokinetic properties.

Absorption: Paracetamol is completely and rapidly absorbed via gastrointestinal tract after oral administration with a peak serum levels occurring in 15 – 45 minutes with a bio- availability of 96% ± 10%. Distribution: The drug is 25% protein-bound. Plasma concentrations do not correlate well with analgesic effect, but do correlate with toxicity. Metabolism: Approximately 90% to 95% is metabolized by hepatic microsomal enzymes. Excretion: Paracetamol is excreted in the urine. The average elimination half-life ranges from 1 to 4 hours. In acute overdose, prolongation of elimination half-life is correlated with toxic effects, half-life greater than 4 hours is associated with hepatic necrosis; greater than 12 hours is associated with coma.

5.3 Preclinical safety data

None known

6.0 Pharmaceutical particulars

6.1 List of excipients

Maize starch, PVP K-30, Purified water, Potassium sorbate, Magnesium stearate and Purified Talc.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 30°C. Protect from light.

Keep all medicines out of reach of children.

6.5 Nature and contents of container

Pack size: Blister packs of 10x10's in unit box and 1000's in HDPE container along with literature insert.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed off in accordance with local requirements.

7.0 Marketing authorisation holder

DAWA Limited
Plot No.7879/8, Baba Dogo Road Rd, Ruaraka.
P.O Box 16633-00620, Nairobi-Kenya.

8.0 Manufacturer

DAWA Limited
Plot No.7879/8, Baba Dogo Road Rd, Ruaraka.
P.O Box 16633-00620, Nairobi-Kenya

9.0 Legal category

Over the counter (OTC).

10. Date of revision of the text

June 2019.