Paratal® Tablets
PARACETAMOL TABLETS

COMPOSITION:
Each tablet contains Paracetamol BP 500mg

PROPERTIES, ACTIONS AND FATE:
Paratal® tablets contain paracetamol, a potent analgesic and antipyretic agent used in the symptomatic management of pain and fever. Paracetamol has no anti-inflammatory effects. The analgesic effects of Paracetamol is due to its action at pain receptors while its antipyretic effects depends on its ability to inhibit the hypothalamic prostaglandin synthetase system which results in the activation of heat loss mechanisms such as sweating and peripheral vasodilation and inhibition of thermogenesis. Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occuring about 10 to 60 minutes after oral administration. It is well distributed into most body tissues and crosses the placenta and is present in breast milk. Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates.

INDICATIONS:
Paratal® tablets are indicated in conditions where analgesic and antipyretic effects are desired. It is used in the management of mild to moderate pain such as headache, dysmenorrhoea, myalgia (muscular pain) and dental pain.
The preparation is of value in the reduction of temperature in the treatment of minor febrile conditions, such as colds or influenza and in the symptomatic treatment of local redness, swelling, pain, and fever, which may occur after immunization of children.

DOSAGE AND ADMINISTRATION:
Paratal® tablets are administered by the oral route.

Dose:
Adults: 500mg to 1g every 4 to 6 hours up to a maximum of 4g daily. It is recommended that if the preparation is used for long-term therapy, then the daily dose should not exceed 2.6g.

Children: 1 to 5 years: 125 - 250mg, three to four times daily (about one- quarter to half a tablet, 3 to 4 times daily).
6 to 12 years: 250-500mg, three to four times daily (Half to one tablet 3 to 4 times daily).

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PRECAUTIONS, WARNING AND ADVERSE EFFECTS:
1. **Paratal® tablets** should be administered with extreme caution to patients with impaired renal or liver function, and to patients taking other drugs that affect the liver.
2. The side-effects of paracetamol are usually mild, although haematological reactions including thrombocytopenia, leucopenia, pancytopenia, neutropenia, and agranulocytosis have been reported. Pancreatitis, skin rashes, and other allergic reactions occur occasionally.
3. Symptoms of paracetamol overdosages 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. Treatment of paracetamol poisoning should involve gastric lavage which should be initiated within 4 hours from the time the overdose was taken.

LEGAL CATEGORY: General Sales Drug (GS) for compliant packs and Pharmacy only (P) for the bulk pack. Schedule 4 (Botswana)

THERAPEUTIC CATEGORY: ATC: N02B (other analgesic and antipyretics)

STORAGE CONDITIONS: Store in a dry place below 30°C. Protect from light. Keep out of reach of children.

SHELF LIFE: As per the product label.

PRESENTATION:
Paratal® tablets In blister packs of 10 x 10's and bulk packs of 1000 tablets

LICENCE HOLDER: LABORATORY & ALLIED LTD.
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Manufactured by:
Laboratory & Allied Ltd.
Plot No. 209/10349, Mombasa Road.
P.O. Box 42875, Nairobi, Kenya.

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