Important information. Please read carefully.

PALAVO

TABLET 650MG

COMPOSITION
Each tablet contains Paracetamol 650mg.

PHARMACODYNAMICS
Paracetamol, a para-aminophenol derivative, has analgesic and antipyretic properties and weak anti-inflammatory activity.

PHARMACOKINETICS
Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. The elimination half-life of paracetamol varies from about 1 to 3 hours. Paracetamol is metabolised mainly in the liver and excreted in the urine mainly as the glucuronide and sulfate conjugates. Less than 5% is excreted as unchanged paracetamol. A minor hydroxylated metabolite (*N*-acetyl-*p*-benzoquinoneimine), is usually produced in very small amounts by cytochrome P450 isoenzymes (mainly CYP2E1 and CYP3A4) in the liver and kidney. It is usually detoxified by conjugation with glutathione but may accumulate after paracetamol overdosage and cause tissue damage.

INDICATIONS
Palavo tablet is given orally for mild to moderate pain and for fever.

DOSAGE AND ADMINISTRATION
Palavo tablet is for oral use only.
To be taken before or after food with a glass of water.

Adults
1 - 1½ tablets every 4-6 hours (not more than 6 tablets in one day unless prescribed by doctor).
If symptoms persist for more than 3 days, consult a doctor.

CONTRAINDICATIONS
Palavo tablet should not be taken if you have known hypersensitivity to Paracetamol.

WARNING AND PRECAUTIONS
Paracetamol should be given with care to patients with impaired kidney or liver function. It should also be given with care to patients with alcohol dependence.

WARNING

This preparation contains PARACETAMOL.
Do not take any other paracetamol containing medicines at the same time.

• **Allergy alert:** Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash.
These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

DRUG INTERACTIONS
The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes. The absorption of paracetamol may be accelerated by drugs such as metoclopramide. Excretion may be affected and plasma concentrations altered when given with probenecid. Colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol.

PREGNANCY AND LACTATION
Pregnancy
Paracetamol is generally considered to be the analgesic of choice in pregnant patients. However, the frequent use of paracetamol (defined as most days or daily use) in late pregnancy may be associated with an increased risk of persistent wheezing in the infant which may persist into childhood.

Lactation
No adverse effects have been seen in breastfed infants whose mothers were receiving paracetamol. The amount of paracetamol distributed into breast milk is too small to be harmful to a breast-fed infant.

SIDE EFFECTS
Adverse effects of paracetamol are rare and usually mild, although haematological reactions including thrombocytopenia, leucopenia, pancytopenia, neutropenia, and agranulocytosis have been reported. Skin rashes and other hypersensitivity reactions occur occasionally.
Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE
Overdosage with paracetamol can result in severe liver damage and sometimes acute renal tubular necrosis. Prompt treatment with acetylcysteine or methionine is essential. Early signs of overdosage (very commonly nausea and vomiting although they may also include lethargy and sweating) usually settle within 24 hours. Abdominal pain may be the first indication of liver damage, which is not usually apparent for 24 to 48 hours and sometimes may be delayed for up to 4 to 6 days after ingestion. Liver damage is generally at a maximum 72 to 96 hours after ingestion. Hepatic failure, encephalopathy, coma, and death may result. Acute renal failure with acute tubular necrosis may develop, even in the absence of severe liver damage. Other non-hepatic symptoms that have been reported following paracetamol overdosage include myocardial abnormalities and pancreatitis.

SHELF-LIFE
The expiry date is indicated on the packaging.

STORAGE CONDITION
Store below 30°C.

PRODUCT DESCRIPTION
Palavo tablet is white, oval, with "XS" and breakline on one side and plain on the reverse.
Available in pack size of 70 tablets per box (10 tablets per blister).

KEEP OUT OF REACH OF CHILDREN/ JAUHI DARI KANAK-KANAK
For further information, please consult your pharmacist or physician.

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Manufacturer, Product Owner and Product Registration Holder:
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