AVADOL tablet 500 mg

Composition: Each tablet contains 500 mg of paracetamol.
Excipients: sodium starch glycolate, sodium lauryl sulphate, pre-gelatinised starch, plasdon K29, Talcum, Colloidal silica, Magnesium Stearate and Opadry White
Description:. White to off-white, round tablet with 500 debossed on one side and plain on the other side.
Pharmacodynamic:
The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis In the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.
Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vaso-dilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin
synthesis in the hypothalamus.

Pharmacokinetic: Oral absorption is rapid and almost complete, it may be decreased if Paracetamol is taken following a high carbohydrate meal. There is no significant protein binding with doses producing plasma concentrations of below 60mcg (μg)/ml, but may reach moderate
levels with high or toxic doses. Approximately 90 - 95% of a dose is metabolised in the liver, primarily by conjugation with glucuronic acid, sulphuric acid and cysteine. An intermediate metabolite, which may accumulate in overdosage after primary metabolic pathways become saturated, is hepatotoxic and possibly nephrotoxic. Half life is 1 to 4 hours; does not change with renal failure but may be prolonged in acute overdosage, in some forms of hepatic disease, in the elderly, and in the neonate; may be somewhat shortened in children. Elimination is by the renal route, as metabolites, primarily conjugates, 3% of a dose may be excreted unchanged. Peak concentration of 10 - 15mcg(μg)/ml have been measured in breast milk, 1 - 2 hours following maternal ingestion of a single 650mg dose Half life in breast milk is 1.35 - 3.5 hours.
INDICATIONS: For relief of headache, fever, pain & discomfort due to cold or flu & toothache and following dental procedures
SIDE-EFFECTS: When given in recommended doses, skin rash and other allergic reactions have been described rarely.
CONTRAINDICATIONS: Patients with a history of hypersensitive to paracetamol and any ingredients of Avadol .
PRECAUTIONS/WARNINGS: Do not give this medicine if the patient is allergic to paracetamol.
Do not exceed the prescribed dose.
Warning: If symptoms persist , please consult your doctor.
This preparation contains paracetamol. Do not give the patient any other paracetamol containing medicines at the same time.
Adult : 1 - 2 tab 3 times or 4 times a day. Maximun: 8 tablet/day
Pregnancy and Lactation: Category A: Paracetamol has been taken by large number of pregnant women and women of childbearing age without any proven increase in frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.
Use in Lactation: Paracetamol is excreted in breast milk in less than 1% of the dose ingested by lactating women. Therefore, maternal ingestion of therapeutic doses does not present a risk to the baby.
Interactions with other medicament:
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 probenecid. Colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol. Drug interaction also reported with warfarin , rifampicin, chloramphenicol, antiepileptic (carbamazepine, phenobrbital, phenytoin or primidone), antiviral (interferon alfa and zidovudine) and probenecid. (Martindale, The Complete Drug Reference, 34th Edition, Page 78)

Serious skin reactions

Rarely, Paracetamol may cause serious skin reactions such as acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Symptoms and treatment for overdosage :

Accidental overdose is usually rare due to the high therapeutic index of the product. Overdose in children may be related to accidental overdose by an adult. Overdose can result in severe liver damage and sometimes acute renal tubular necrosis. Toxic symptoms include vomiting, abdominal pain, hypotension, sweating, central stimulation with exhilaration and convulsions in children, drowsiness, respiratory depression, cyanosis and coma. In adults, hepatoxicity may occur after ingestion of a single dose of paracetamol 10 to 15 g (20 to 30 tablets or 10 to 15 times the normal dose); a dose of 25 g (50 tablets) or more is potentially fatal. Symptoms during the first two days of acute poisoning by paracetamol do not reflect the potential seriousness of the intoxication. Major manifestations of liver failure such as jaundice, hypoglycaemia and metabolic acidosis may take at least three days to develop.

Treatment Prompt treatment is essential even when there are no obvious symptoms. In cases of overdosage, methods of reducing absorption of ingested drug are important. Prompt administration of activated charcoal 50 g in 150 mL of water and 150 mL sorbitol 50% solution by mouth may reduce absorption. It is recommended that intravenous fluids such as Normal Saline be given concurrently. Gastric lavage is indicated if the patient is unwilling or unable to drink an activated charcoal/sorbitol mixture. If the history suggests that paracetamol 15 g or more has been ingested, administer the following antidote. Intravenous acetylcysteine 20%. Administer acetylcysteine immediately without waiting for positive urine test or plasma level results if 8 hours or less since overdose ingestion. Initial dose 150 mg/kg over 15 minutes, followed by continuous infusion of 50 mg/kg in glucose 5% 500 mL over four hours and 100 mg/kg in glucose 5% 1 L over 16 hours. If more than 8 hours have elapsed since the overdosage was taken, the antidote may be less effective.

Packing: Strip pack of 10's per strip. 10'sx2, 10'sx20 per box

Store at room temperature below 30^{0}C. Protect from light

Shelf-life: Three years from the date of manufacture.

KEEP OUT OF REACH OF CHILDREN.

Manufactured by:

AV Manufacturing Sdn.bhd.

Lot 10621(Pt16700), Jln Permata 2, Arab Malaysian Industrial Park, 71800 Nilai Negeri Sembilan, Malaysia

Singapore Licence holder:

JOYSON PTE LTD.

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