SCHEDULING STATUS: S1

PROPRIETARY NAME (AND DOSAGE FORM):

PACKAGE INSERT

VON PARACETAMOL 500mg (TABLETS)

COMPOSITION:
Each tablet contains:

Paracetamol		500 mg
Preservatives:	Nipastat	0,1% m/m
	Benzoic Acid	0,06% m/m

TARTRAZINE free

PHARMACOLOGICAL CLASSIFICATION:
A 2.7 Anti-pyretic or anti-pyretic and anti-inflammatory analgesics

PHARMACOLOGICAL ACTION:
Paracetamol has analgesic and anti-pyretic actions.

INDICATIONS:
For the relief of mild to moderate pain and fever such as headaches, toothache and pain associated with colds and flu.

CONTRA-INDICATIONS:
Hypersensitivity to paracetamol.
Severe liver function impairment.

WARNINGS:
Dosages in excess of those recommended may cause severe liver damage. Patients suffering from liver or kidney disease should take paracetamol under medical supervision. Do not use continuously for more than 10 days without consulting a doctor. Excessive and prolonged use of this medicine may be dangerous.

In the event of overdosage or suspected overdose and not withstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

DOSAGE AND DIRECTIONS FOR USE:
DO NOT EXCEED THE RECOMMENDED DOSE
Adults:
One or two tablets repeated every 3-4 hours if necessary, but not more than 8 tablets to be taken in any 24 hour period.
Children 6-12 years:
Half to one tablet repeated every 3-4 hours if necessary, but not more than 4 doses in any 24 hour period.
Children under 6 years:
Not recommended. Paracetamol syrup should rather be considered for use if such a medicine is necessary.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Skin rashes and other allergic reactions may occur. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied be fever and mucosal lesions. The use of paracetamol has been associated with the occcurrence of neutropenia, pancytopenia and leucopenia.
Special precautions:
1. Consult a doctor if no relief is obtained from the recommended dosage.
2. Store in a safe place out of reach of children.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT:
Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person to a hospital directly. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed. Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 -10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.
Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage. Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.
Treatment for Paracetamol overdosage:
Although evidence is limited it is recommended that any adult person who has ingested 5 - 10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration. **N-acetylcysteine** should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken.
IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours, and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.
Orally: Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by a 70 mg/kg solution every 4 hours for 17 doses.
A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours, unless high, may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the normogram below. Those, whose plasma paracetamol levels are above the "normal treatment line", should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the "high risk treatment line". Prothrombin index correlates best with survival.
Monitor all patients with significant ingestions for at least ninety six hours.

IDENTIFICATION:
Round yellow tablets, scored on one side.

PRESENTATION:
HDPE containers of 1000 and 5000 tablets.

STORAGE INSTRUCTIONS:
Store in a well-closed container protected from light. Store below 25°C.
Exposure to air should be minimal.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
B/2.7/1480

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
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