APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS:

S0 (less than 100 ml), S1 (more than 100 ml)

PROPRIETARY NAME (AND DOSAGE FORM):

FEVERPAIN (SYRUP)

COMPOSITION:

Each 5 ml contains:

Paracetamol		120,00 mg
Preservatives:	Methyl hydroxybenzoate	0,09 % m/v
	Propyl hydroxybenzoate	0,01 % m/v
	Ethanol	11,04 % v/v

Other ingredients: Propylene glycol, liquid glucose, sodium saccharin, green colourant CI: 42090, 47005, 44090, apple flavour H&R 4660, purified water.

Contains sugar.

PHARMACOLOGICAL CLASSIFICATION:

A 2.7 Antipyretic or antipyretic and anti-inflammatory analgesics.

PHARMACOLOGICAL ACTION:

Paracetamol has analgesic and antipyretic actions.

INDICATIONS:

For the relief of mild to moderate pain and fever.

CONTRAINDICATIONS:

Sensitivity to paracetamol. Severe liver function impairment.

WARNINGS AND SPECIAL PRECAUTIONS:

This product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Dosages in excess of those recommended may cause severe liver damage.

1. Consult a doctor if no relief is obtained from the recommended dosage.
2. Do not use continuously for longer than 10 days without consulting a doctor.
3. Store in a safe place out of reach of children.
4. Patients suffering from liver or kidney disease should take paracetamol under medical supervision.

INTERACTIONS:

Interactions with **FEVERPAIN** have not been established.

PREGNANCY AND LACTATION:

The safety and efficacy of **FEVERPAIN** in pregnancy and lactation have not been established.

DOSAGE AND DIRECTIONS FOR USE: (Note: 1 Medicine measure = 5 ml)

DO NOT EXCEED THE RECOMMENDED DOSE.

Children:

9 – 12 years	=	10 – 20 ml
5 – 8 years	=	5 – 10 ml
1 – 4 years	=	2,5 – 5 ml
3 months – 1 year	=	2,5 ml

Repeat dosage 4 – 6 hourly if necessary but not more than 4 doses in 24 hours.

SIDE EFFECTS:

Sensitivity reactions resulting in reversible skin rash or blood disorders e.g. neutropenia, leucopenia, pancytopenia may occur.

The skin rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. 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 medicines 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 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 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 overdosage as soon as possible, preferably within 8 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.
An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given **intravenously** over 15 minutes, followed by an infusion of 50 mg/kg in 500 ml dextrose injection over the next 4 hours, and then 100 mg/kg in 1 000 ml dextrose injection over the next 16 hours. **The volume of intravenous fluids should be modified for children.**

Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every 4 hours for 17 doses.

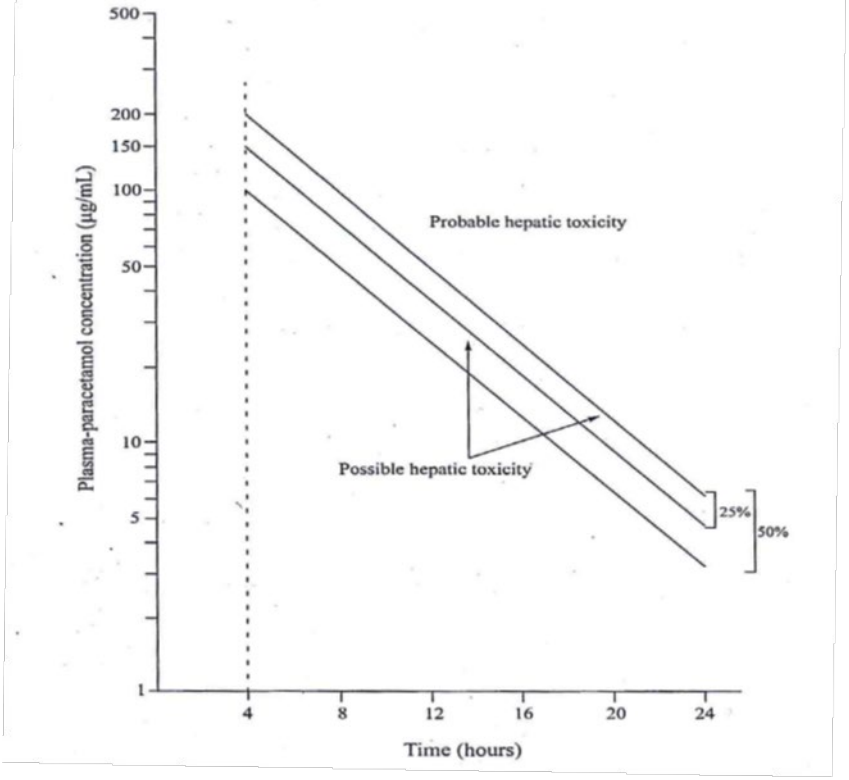
A plasma paracetamol level should be determined 4 hours after ingestion in all cases of suspected overdosage. Levels done before 4 hours may be misleading. Patients at risk of liver

damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below. The nomogram should be used only in relation to a single acute ingestion.

Those whose plasma paracetamol levels are above the “normal treatment line”, should continue N-acetylcysteine treatment with 100 mg/kg IV over 16 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 ingestion for at least 96 hours.

Figure 1. A semi-logarithmic plot of plasma-paracetamol concentration against hours after ingestion.



IDENTIFICATION:

A clear, green syrup with an apple flavour.

PRESENTATION:

50 ml or 100 ml amber/white PVC or HDPE bottles, or 50 ml or 100 ml amber glass bottles, or 500 ml amber/white PVC bottles, and 2,5 litre amber HDPE bottles.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in well-closed containers, protected from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

X/2.7/392

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Shanur Healthcare (Pty) Ltd

Loch House Unit 3

3A Eton Road

Parktown

Johannesburg, 2193

DATE OF PUBLICATION OF THE PACKAGE INSERT:

To be allocated.