SCHEDULING STATUS:

S0 - Pack sizes with less than 25 capsules

S1 - Pack sizes with or more than 25 capsules

PROPRIETARY NAME: **PANADO CAPSULES**

(AND DOSAGE FORM) **(CAPSULE)**

COMPOSITION:

Each capsule contains 500 mg paracetamol and 0,12 % m/m potassium sorbate as preservative.

Sugar free

List of excipients: Maize starch, colloidal silica, magnesium stearate.

Capsule components: gelatin, titanium dioxide.

PHARMACOLOGICAL CLASSIFICATION:

A 2.8 Analgesic combinations

PHARMACOLOGICAL ACTION:

Paracetamol has analgesic and antipyretic actions

INDICATIONS:

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

CONTRAINDICATIONS:

Hypersensitivity to paracetamol or any of the excipients.

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.

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.

Consult a doctor if no relief is obtained from the recommended dosage.

Store in a safe place out of reach of children.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

DO NOT EXCEED THE RECOMMENDED DOSE

Adults: One or two capsules repeated every 3 to 4 hours if necessary, but not more than 8 capsules to be taken in any 24 hour period.

Children 9 to 12 years: One capsule repeated every 3 to 4 hours if necessary, but not more than 4 doses in any 24 hour period.

Children under 9 years: Not recommended.

SIDE EFFECTS

Skin rashes and other allergic reactions may occur. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions. The use of paracetamol has been associated with the occurrence of neutropenia, pancytopenia and leucopenia.

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 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 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

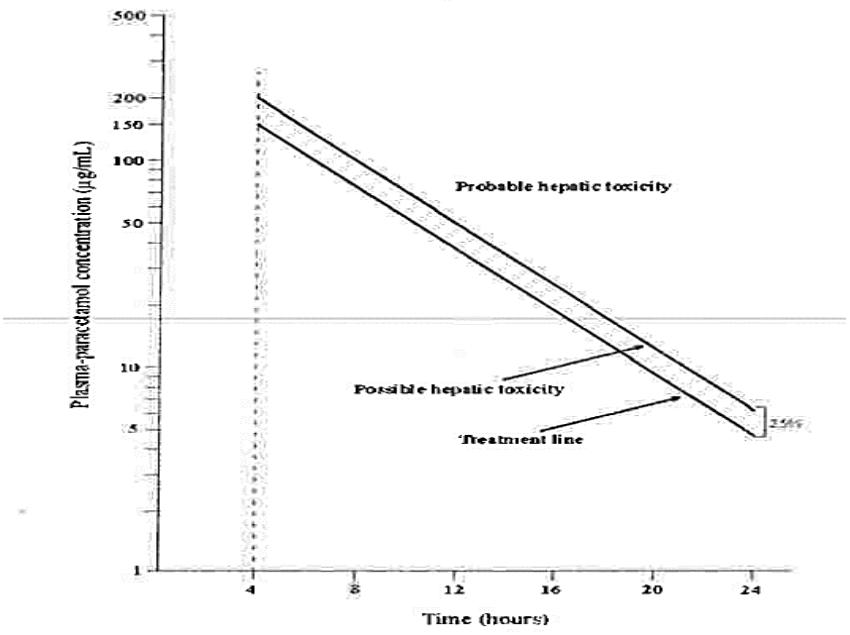
Treatment for paracetamol overdosage:

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. 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 four hours, and then 100 mg/kg in 1 000 ml dextrose injection over the next sixteen hours. **The volume of intravenous fluid 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 four hours for seventeen doses.

A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four 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.



Source: Martindale: The Complete Drug Reference -37th Edition.

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:

A hard gelatin capsule, size No. 0, opaque white body and cap, with "**Panado 500**" printed in red.

PRESENTATION:

Blister packs of 20 and 30 sealed capsules.

STORAGE INSTRUCTIONS:

Store at or below 25 ^{o}C in a well-closed container protected from light. Exposure to air should be kept to a minimum.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

S/2.8/57

Namibia: 90/2.8/00154 – NS0: 25 pack size; NS1: >25 pack size
Botswana: B9311205 – 3 or 4 (pack size <30)

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

Adcock Ingram Limited

1 New Road, Erand Gardens,

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Private Bag X69, Bryanston, 2021

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

August 1984