SCHEDULING STATUS:

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PROPRIETARY NAME (AND DOSAGE FORM) : PANADO® INFANT DROPS (DROPS)

COMPOSITION:

Each 0,6 ml contains:

Paracetamol 60 mg

Excipients: Citric acid anhydrous; glycerine; polyethylene glycol;

propylene glycol; sodium chloride; sodium citrate anhydrous; peppermint oil; FD&C Yellow No. 6;

FD&C yellow No. 10; FD&C Blue No. 1; purified water

Preservatives:

Methylparaben 0,085 % m/v

Propylparaben 0,015 % m/v

Contains sweetener:

Sodium Saccharin 450 4,50 mg

Alcohol and Sugar free.

Tartrazine free.

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:

Hypersensitivity to paracetamol or to any of the ingredients of **PANADO INFANT DROPS**

Severe liver function impairment.

WARNINGS AND SPECIAL PRECAUTIONS

PANADO INFANT DROPS 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.

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

Do not use continuously for more than 10 days without consulting a doctor:

Store in a safe place out of reach of children.

DOSAGE AND DIRECTIONS FOR USE:

DO NOT EXCEED THE RECOMMENDED DOSE.

Infants: 3 months to 1 year: 0,6 to 1,2 ml (60 mg to 120 mg)

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

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 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 to10 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.

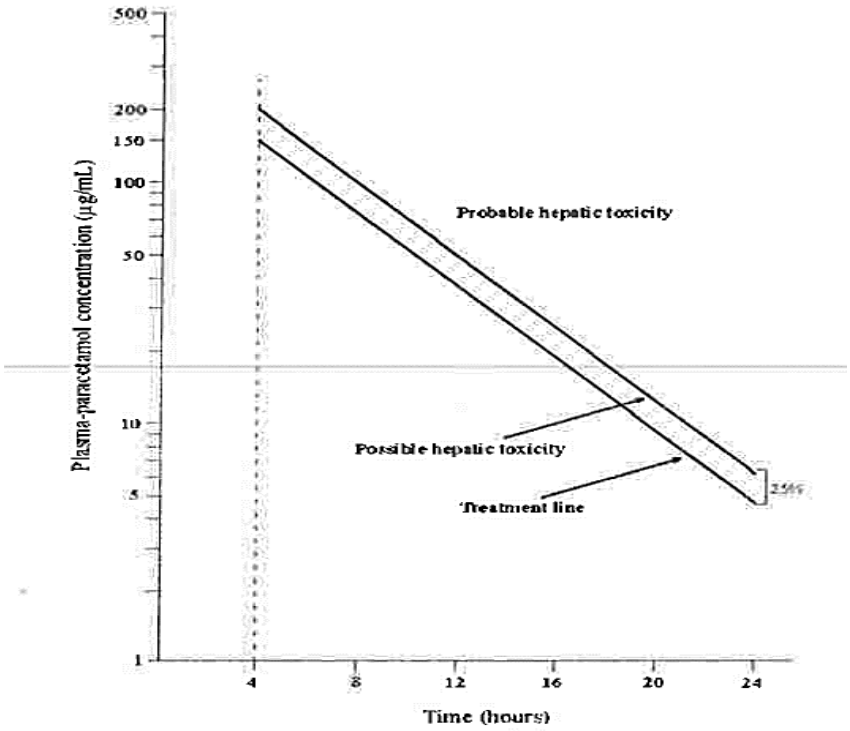
Treatment of paracetamol overdosage:

Although evidence is limited it is recommended that any adult person who has ingested 5 to 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 4 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.



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:

Sweet, peppermint flavoured, green syrup.

PRESENTATION:

20 ml Clear glass bottle with closure and a calibrated dropper.

STORAGE INSTRUCTIONS:

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

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

V/2.7/209

Namibia	NS0	05/2.7/0159
Botswana	S4	B9311240

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

Adcock Ingram Limited

1 New Road, Erand Gardens,

Midrand, 1685

Private Bag X69

Bryanston, 2021

www.adcock.co.za

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