SCHEDULING STATUS:

S0 - Pack sizes with less than 25 tablets

S1 - Pack sizes with or more than 25 tablets

PROPRIETARY NAME: **PANADO TABLETS**

(AND DOSAGE FORM) **(TABLET)**

COMPOSITION:

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

List of excipients: colloidal silica, magnesium stearate and maize starch.

Sugar free

PHARMACOLOGICAL CLASSIFICATION:

A 2.7 Antipyretics or antipyretic and anti-inflammatory analgesics

PHARMACOLOGICAL ACTION:

Paracetamol has analgesic and antipyretic actions. It acts predominantly by inhibiting prostaglandin synthesis.

Following oral administration, paracetamol is well absorbed, with peak plasma concentrations obtained after 0, 5 to 1 hour.

Once absorbed, the plasma half-life is about 2 hours.

Plasma protein binding is variable.

Paracetamol is metabolised in the liver primarily by conjugation with glucuronic acid (about 60 %), sulphuric acid (about 35 %) and cysteine (about 3 %).

Paracetamol is renally excreted primarily as conjugated metabolites.

INDICATIONS:

PANADO TABLETS is indicated for the symptomatic treatment of mild to moderate pain and fever.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients of **PANADO TABLETS**.

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.

Consult a medical practitioner if pain or fever persists or gets worse at the recommended dosage, if new symptoms occur or if redness and swelling is present, as these could be signs of a more serious condition.

Do not use this product continuously without consulting a medical practitioner:

for pain – for more than seven days in adults (5 days for children);

for fever – for more than 3 days.

Patients suffering from hepatitis or alcoholism, or recovering from any form of liver disease, should not take excessive quantities of **PANADO TABLETS**.

Use with caution in renal disease.

INTERACTIONS

Hepatotoxic medicines - increased risk of hepatotoxicity.

Enzyme inducing medicines - increased risk of hepatotoxicity. Possible decrease in therapeutic effects of **PANADO TABLETS.**

Metoclopramide and domperidone - absorption of **PANADO TABLETS** may be accelerated.

Cholestyramine - absorption of **PANADO TABLETS** is reduced if given within one hour of cholestyramine.

Prolonged concurrent use of **PANADO TABLETS** with salicylates increases the risk of adverse renal effects.

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 tablet every 3 hours or one to two tablets every 4 to 6 hours while symptoms persist. Do not exceed 4 gram in 24 hours.

Children 6 to 12 years: Half to one tablet while symptoms persist, to be repeated every 4 hours if needed to a maximum of 4 doses per 24 hours for not longer than 5 days.

Children under 6 years: Not recommended. Paracetamol syrup should rather be considered for use if such a medicine is necessary.

SIDE EFFECTS

Blood and lymphatic system disorders:

Less frequent: Agranulocytosis, thrombocytopenia, leucopenia, pancytopenia, neutropenia, anaemia

Gastrointestinal disorders:

Less Frequent: Pancreatitis

Hepatobiliary disorders:

Less Frequent: Hepatitis

Renal and urinary disorders:

Less frequent: Renal colic, renal failure and sterile pyuria.

Skin and subcutaneous tissue disorders:

Less frequent:

Dermatitis, skin rashes, and other allergic reactions. The rash is usually erythematous or urticarial but sometimes more serious and 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 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.

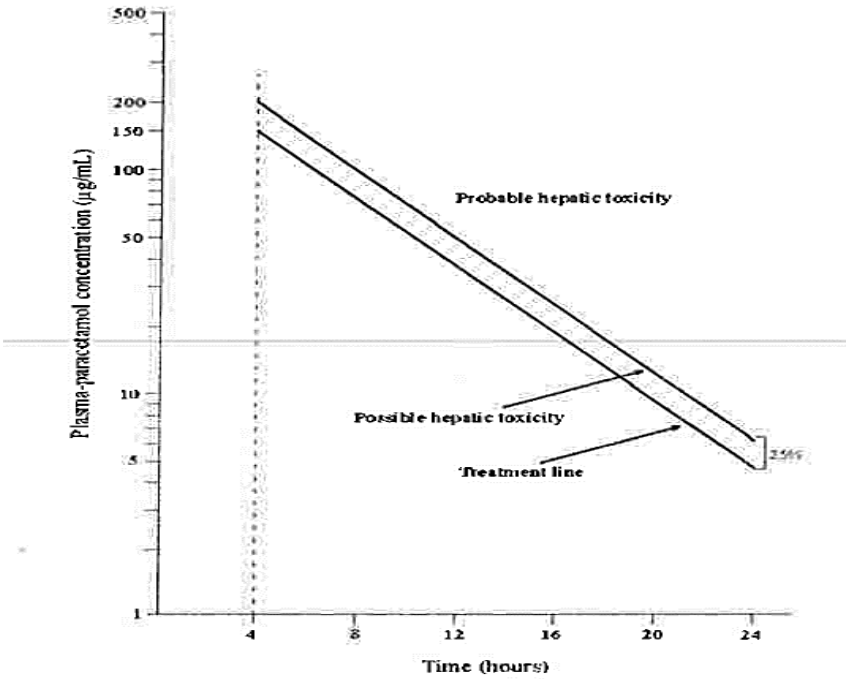
Treatment for paracetamol overdosage:

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. 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:

Round, white, biconvex tablets, 13 mm in diameter and 5 mm in thickness. Name PANADO impressed on face. Reverse side is scored and carries a dot in the centre of the top hemisphere and a 1 mm indentation in the centre of the periphery of the lower hemisphere.

PRESENTATION:

Polypaper strips of 2 tablets

2 Polypaper strips of 2 tablets each in a carton

PVC/Aluminium foil blister packs of 12, 24 and 100 tablets

White polypropylene tracer packs of 24, 50 and 100 tablets

White polypropylene securitainers of 10, 20 and 500 tablets

White HDPE Spartan containers of 24, 50 and 100 tablets

White, round HDPE buckets of 5 000 tablets

White, square HDPE cans of 5 000 tablets.

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:

B/2.8/858

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

Adcock Ingram Limited

1 New Road, Erand Gardens,

Midrand, 1685

Private Bag X69, Bryanston, 2021

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

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