

PRODUCT LITERATURE

PANAMOL SYRUP 120MG/5ML

Each 5 ml contains:

Paracetamol 120mg

Preservative:

Methyl Paraben 0.1% w/v

Propyl Paraben 0.01% w/v

Description

Orange coloured clear syrup with sweet taste and fruity odour.

Pharmacodynamic properties

Paracetamol has analgesic and antipyretic actions probably due to the inhibition of prostaglandin biosynthesis.

Pharmacokinetic properties

Paracetamol is readily absorbed from the gastro-intestinal tract and peak plasma concentrations usually occur 30 minutes to 2 hours after ingestion.

Paracetamol is metabolised in the liver and largely excreted in the urine as sulphate and glucuronide conjugates. Less than 5% is excreted unchanged.

The elimination half-life varies from about 1 to 4 hours.

Indication

To relieve mild to moderate pain and to reduce fever in many conditions including headache, toothache, teething, feverishness, colds and influenza and following vaccination.

Recommended Dosage

CHILDREN: up to 1 year: 60 - 120 mg. 1 - 5 years: 120 - 240 mg.

6 - 12 years: 240 - 480 mg per dose.

Repeat every 4 - 6 hours when necessary. Maximum of 4 doses in 24 hours

Route of administration

Oral

Contraindications

Contra-indicated in patients with a known hypersensitivity to paracetamol or any of the other constituents.

Warning and Precautions

This preparation contains PARACETAMOL. Do not take any other paracetamol containing medicines at the same time.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

- Keep out of reach of children.
- Do not take if allergic to paracetamol.
- Patients should contact their health care provider if symptoms persist (if the pain lasts for more than 10 days, if there is redness or fever lasts more than 3 days).
- Paracetamol should be given with care to patients with impaired kidney or liver function.
- Larger doses should be avoided in patients with hepatic impairment. Paracetamol overdose may harm the liver.
- Do not exceed recommended dose.
- It should be given with care to patients with alcohol dependence.
- Paracetamol provides symptomatic relief only, additional therapy to treat the cause of the pain or fever should be instituted when necessary.

- Paracetamol should be used with care in patients with severe renal or hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.
- Patients should be advised not to take other paracetamol containing products concurrently.

Effects on Ability to Drive and Use Machines:

No adverse effects known.

Interactions with other medicaments

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Patients who have taken barbiturates, tricyclic antidepressants and alcohol may show diminished ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged.

Alcohol can increase the hepatotoxicity of paracetamol overdose and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol.

Chronic ingestion of anticonvulsants or oral steroid contraceptives induces liver enzymes and may prevent attainment of therapeutic paracetamol levels by increasing first pass metabolism or clearance.

Pregnancy and Lactation

Pregnancy

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

Lactation

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Side Effect and Adverse Reaction

Adverse effects of paracetamol are rare and usually mild, although haematological reactions have been reported. Skin rashes and other hypersensitivity reactions occur occasionally.

Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

Symptoms and Treatment of Overdose

Early symptoms of paracetamol overdose include pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is possible in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue. Immediate treatment is essential in the management of Paracetamol overdose.

Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Any patient who has ingested around 7.5g or more of paracetamol in the preceding 2 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose may be required. General supportive measures must be available.

Packing

Packed in plastic container of 60 ml.

Storage Condition

Store below 30°C in a dry place, protected from direct light.
Keep away from reach of children.

SHAKE WELL BEFORE USE**Expiry Date**

2 years from date of manufacture.

Name and Address of Product Registration Holder/ Manufacturer:

TERAPUTICS SDN. BHD. (590500-W)

Lot 10 & 11, PERDA Industrial Park,
Lorong IKS Simpang Ampat B,
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Name and Address of Distributors:

ZONTRON PHARMACEUTICALS SDN.BHD. (445695-T)

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