

PORO[®] SUSPENSION 250MG/5ML

(PINEAPPLE FLAVOUR)

Each 5ml contains:

Ingredient(s):

Paracetamol 250mg

Preservatives:

Methyl Paraben 0.18%w/v

Propyl Paraben 0.02%w/v

Pharmacodynamics:

The analgesic action of Paracetamol involves peripheral and central influences. Antipyretic is mediated through hypothalamic heat regulating centers. Paracetamol inhibits prostaglandin synthetase.

Pharmacokinetics:

Therapeutic doses of Paracetamol have negligible effects on the cardiovascular respiratory systems; however, toxic doses may cause circulatory failure and rapid, shallow breathing.

Indication(s):

For the relief of fever and mild to moderate pain.

Dosage and Administration:

1 ~ 5 years : 2.5ml ~ 5ml (½ ~ 1 teaspoon)

6 ~ 12 years : 5ml ~ 10ml (1 ~ 2 teaspoon)

Doses may be repeated every 4 ~ 6 hours when necessary.

(max of 4 doses in 24 hours).

To be taken orally.

Shake well before use

Contraindications:

Hypersensitivity to Paracetamol.

Precaution(s) / Warning(s):

If fever persists for more than 3 days or recurs, or if pain continue for more than 5 days, consult a physician immediately. Use with caution in patients with anemia or with cardiac, pulmonary, renal or hepatic disease.

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.

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

Drug Interaction:

1. Concurrent chronic, high-dose administration of Paracetamol with anticoagulants may increase the anticoagulant effect.

2. Administration of Paracetamol with Aspirin increases blood concentration of unhydrolysed aspirin.

Pregnancy and Lactation

Fertility

There is no information relating to the effects of this medicine on fertility.

Pregnancy

A large amount of data on pregnant women indicate neither malformative, nor foeto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

When given to the mother in therapeutic doses (1g single dose),

paracetamol crosses the placenta into foetal circulation as early as 30 minutes after ingestion and is metabolised in the foetus by conjugation with sulfate and increasingly with glutathione.

Breast-feeding

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

Side Effect(s) / Adverse Reaction(s):

Side effects of Paracetamol are usually mild, though hematological reactions have been reported. Skin rashes and other allergic reactions occur occasionally.

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

Symptoms and Treatment For Overdosage, and Antidote(s):

Liver damage is possible in adults and adolescents (≥12 years of age) who have taken 7.5g 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. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors

If the patient

a) Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St. John's Wort or other drugs that induce liver enzymes.

or

b) Regularly consumes ethanol in excess of recommended amounts.

or

c) Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, hyperhidrosis, malaise, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. This may include hepatomegaly, liver tenderness, jaundice, acute hepatic failure and hepatic necrosis.

Abnormalities of glucose metabolism and metabolic acidosis may occur. Blood bilirubin, hepatic enzymes, INR, prothrombin time, blood phosphate and blood lactate may be increased.

In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Haemolytic anaemia (in patients with glucose-6-phosphate dehydrogenase [G6PD] deficiency): Haemolysis has been reported in patients with G6PD deficiency, with use of paracetamol in overdose.

Management

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. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required, the patient should be given intravenous N-acetylcysteine in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

Storage Condition(s):

Keep in an airtight container. Store at temperature below 30°C. Protect from light and moisture. Keep medicine out reach of children.

Shelf-Life:

3 years from date of manufacture.

Product description and Packing(s):

A yellow color, pineapple flavored suspension.
Plastic bottles of 100mL.

SUSPensi PORO® 250MG/5ML (PERISA NANAS)

Setiap 5ml mengandungi:

Bahan Aktif:

Paracetamol 250mg

Bahan pengawet:

Methyl Paraben 0.18%w/v

Propyl Paraben 0.02%w/v

Indikasi:

Untuk melegakan kesakitan yang ringan dan sederhana serta mengurangkan demam.

Dos:

Kanak-kanak :

1 ~ 5 tahun : 2.5ml ~ 5ml (½ ~ 1 camca teh)

6 ~ 12 tahun : 5ml ~ 10ml (1~2 camca teh)

Dos boleh diulang setiap 4 - 6 jam jika perlu sahaja.
(maksimum 4 dos dalam 24 jam).

Goncang sebelum minum

伯樂懸液 250MG/5ML (黃梨味)

每5ml含:

成分:

Paracetamol 250mg

防腐劑:

Methyl Paraben 0.18%w/v

Propyl Paraben 0.02%w/v

適應症:

用于缓解发烧和轻度至中度疼痛。

劑量:

年齡(歲)	1~5歲	6~12歲
劑量 (茶匙)	2.5~5ml (½~1)	5~10ml (1~2)

每4~6小時服用一次，一天不能超過4次。



Manufacturer and Product Registration Holder:

Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)

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