# hovid-Paracetamol
# Suspension 250 mg / 5 ml (SUGAR FREE)

VIPAR07-var

## DESCRIPTION
Pink, viscous suspension with raspberry flavour.

## COMPOSITION
Each 5 ml contains:
Paracetamol 250 mg

## ACTIONS AND PHARMACOLOGY
Paracetamol is a centrally acting analgesic and antipyretic with minimal anti-inflammatory properties.

**Analgesic:**
The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (specifically cyclooxygenase (COX)-2) and, to a lesser extent, through a peripheral action by blocking pain-impulse generation.

The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.

**Antipyretic:**
Paracetamol act centrally on the hypothalamic heat-regulating center to produce peripheral vasodilatation resulting in increase blood flow through the skin, sweating and heat loss. Paracetamol reduces fever by inhibiting the formulation and release of prostaglandins in the CNS and by inhibiting endogenous pyrogens at the hypothalamic thermoregulator center.

## PHARMACOKINETICS
Following oral administration paracetamol is rapidly absorbed.

Paracetamol absorption takes place mainly in the small intestine and therefore the rate of absorption is depending on the rate of gastric emptying. It has been shown that drugs which delay gastric emptying also delay the absorption of paracetamol whereas metoclopramide (a drug which increases the rate of gastric emptying) accelerates absorption of the analgesic through the total amount absorbed doses not increase.

The presence of food in the stomach has also been reported to reduce the rate of absorption of paracetamol. Alterations in gastric pH have no appreciable effect on paracetamol absorption. During absorption, the amount of paracetamol which is inactivated is negligible and it has been shown that paracetamol does not affect gastric mucosal permeability and does not produce mucosal bleeding.

Peak plasma concentrations are reached 1 hour after absorption. The plasma half life is 1 to 3 hours.

Paracetamol penetrates the brain and is present in breast milk of human.

Paracetamol is metabolized by the microsomal enzyme system of the liver. This metabolism is mainly to the glucuronide and sulphate conjugates, accounting for approximately 49% and 26% of the ingested dose respectively. About 4% is excreted as free paracetamol. Other minor pathways include the production of catechol derivatives and cysteine conjugates (via glutathione). Paracetamol excretion is rapid and occurs via the urine.

## INDICATION
Indicated for the relief of fever, headache and symptoms of cold and flu, toothache, discomfort of teething and fever after vaccination.

## CONTRAINDICATION
- Hypersensitivity to paracetamol or any of the other ingredients/ components of the product
- Severe and active hepatic impairment

## WARNINGS AND PRECAUTIONS

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

- 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.
- Large doses should be avoided in patients with hepatic impairment. Paracetamol overdose may harm the liver.
- Do not exceed recommended dose.
- Paracetamol provides symptomatic relief only, additional therapy to treat the cause of the pain or fever should be instituted when necessary.
- 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.

**Effects on Ability to Drive and Use Machines**
It is unlikely to impair a patient's ability to drive or use machinery.

## PREGNANCY AND LACTATION
**Pregnancy:**
- Considered to be the analgesic of choice in pregnant patients.
- Although it crosses placenta, paracetamol is considered to be safe in normal therapeutic doses for short-term use as a minor analgesic/antipyretic in pregnancy.

**Lactation:**
- Excreted in breast milk.
- Maternal ingestion of paracetamol in normal therapeutic doses does not appear to present a risk to the nursing infant.

## DRUGS INTERACTIONS
- The use of drugs which induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants and alcohol, may increase the hepatotoxicity of paracetamol, particularly after overdosage.
- 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 daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.
- Regular use of paracetamol possibly reduces metabolism of zidovudine (increased risk of neutropenia).

- Drugs that induce hepatic microsomal enzymes such as anticonvulsants and oral contraceptives may increase the extent of metabolism of paracetamol resulting in reduced plasma concentrations of the drug and a faster elimination rate.

## MAIN SIDE/ ADVERSE EFFECTS

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.

## OVERDOSE AND TREATMENT

**Symptoms:**
In the first 24 hours, paracetamol overdose symptoms typically 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 take place. In cases of 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.

**Treatment:**
Immediate treatment is crucial in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical care. 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.

Activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol levels 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. In cases where vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital.

## DOSAGE AND ADMINISTRATION

Oral.
hovid-Paracetamol Suspension 250 mg / 5 ml (Sugar Free) may be taken with or without food.

**hovid-Paracetamol Suspension 250 mg / 5 ml (Sugar Free)**

If you know the body weight of your child, it's always more accurate to use the weight to arrive at the correct dose. Please refer below.

Using the body weight of your child, you can calculate the dose of hovid-Paracetamol Suspension 250 mg / 5 ml (Sugar Free) your child needs. Calculation is based on recommended dose of 15 mg per body weight in kg (BW).

Table below provides the dose of hovid-Paracetamol Suspension 250 mg / 5 ml (Sugar Free) to be given, based on body weight:

| Child's Weight | | hovid-Paracetamol Suspension 250 mg / 5 ml (Sugar Free) |
|---|---|---|
| In kg | In lb | |
| 10 | 22 | 3 ml |
| 15 | 33 | 4.5 ml |
| 20 | 44 | 6 ml |
| 30 | 66 | 9 ml |

Note: 1 kg = 2.2 lb

To be taken 3 to 4 times per day or when necessary.

Minimum dosing interval is 4 hours. No more than 4 doses in any 24-hour period. Maximum duration of continued use without medical advice is 3 days.

Maximum daily dose: 60mg/kg presented in divided doses of 10 - 15 mg/kg throughout the 24-hour period (not more than 4 doses).

Not recommended in children under 1 month.

For children under 3 months, if fever persists for more than 24 hours (4 doses), seek medical advice. This is to ensure that fever that may be due to a serious infection is quickly diagnosed.

The information given here is limited. For further information, consult your doctor or pharmacist.

Storage:
Store below 30˚C. Protect from light and freezing.

Presentation/ Packing:
Suspension 250 mg / 5 ml x 60 ml, 120 ml.

Product Registration Holder/ Manufactured by: HOVID Bhd.
121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

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