

IKOP® PARACETAMOL HONEY SUSPENSION

Paracetamol 250 mg/5 mL

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What IKOP® Paracetamol Honey Suspension is used for

Paracetamol is used for symptomatic relief of:

- Fever
- Aches and pain of flu
- Toothache
- Discomfort of teething and fever after vaccination

How IKOP® Paracetamol Honey Suspension works

The suspension contains an active ingredient, which is paracetamol together with honey. Paracetamol works by relieving fever, symptoms of cold and influenza, teething pain and headache. Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Before you use IKOP® Paracetamol Honey Suspension

-When you must not use it

Do not take this medicine if you have an allergy to paracetamol, any of the other ingredients listed at the end of this leaflet and any other similar medicines.

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 sign of a serious condition.

Adverse Effect: Cutaneous hypersensitivity reactions including skin rashes, angioedema, Steven Johnson/toxic epidermal necrosis have been reported.

If any of these apply to you, get advice from a doctor or pharmacist.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

-Before you start use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- asthma
- allergy
- blood disorder
- severe kidney or liver impairment

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking IKOP® Paracetamol Honey Suspension.

-Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or

health food shop. Some medicines and IKOP® Paracetamol Honey Suspension may interfere with each other.

These include:

Paracetamol should not to be taken concomitantly with alcohol, cholestyramine (reduces absorption of Paracetamol), Warfarin (prolonged use of Paracetamol enhances Warfarin), and Metoclopramide and Domperidone (accelerate absorption of Paracetamol (enhanced effect)).

These medicines may be affected by IKOP® Paracetamol Honey Suspension or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking this medicine.

-Pregnant and lactating women

Clinical data in pregnant and lactating woman is limited. Safety for its use has not been established. Therefore the potential benefit of the product should be weighed against the possible risks to the mother and fetus.

How to use IKOP® Paracetamol Honey Suspension

-How much to use

Shake well before use

It is more accurate to use the body weight of your children to calculate the correct dose of paracetamol your child needs.

Calculation is based on recommended dose of 15mg paracetamol per body weight (kg). The calculation for dose is;

$$\text{Dose(ml)} = \text{Weight(kg)} \times 15\text{mg} \times \frac{5\text{ml}}{250\text{mg}}$$

The below guide is based on the average weight-age grid of children.

Weight (kg)	Age	Dose (mg)	Dose (ml)
20	6	300	6.0
22-28	7-9	330-420	6.5-8.5
32-40	10-12	480-600	9.5-12.0

Do not give more than 4 times daily

-When to use it

Your doctor will decide when it is appropriate for you to take IKOP® Paracetamol Honey Suspension.

-How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Symptoms

Toxic symptoms include vomiting, abdominal pain, low blood pressure, sweating, central brain stimulation with exhilaration and convulsions in children, drowsiness, breathing difficulties, cyanosis (abnormal blue discoloration of the skin), liver failure. The most serious adverse effect of acute overdose of paracetamol is a dose-dependent, potentially fatal hepatic necrosis. Clinical and laboratory evidence of hepatotoxicity may be delayed for up to one week. Major manifestations of liver failure such as jaundice, hypoglycemia and metabolic acidosis may take at least 3 days to develop.

Immediately telephone your doctor for advice, or go to Accident and Emergency department at the nearest hospital, if you think that you or anyone else may have taken too much IKOP®

Paracetamol Honey Suspension. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Treatment

Empty the stomach with gastric lavage or activated charcoal administration. If the history suggests that 15 g paracetamol or more has been ingested, administer one of the following antidotes:

Acetylcysteine 20% i.v.: Administer intravenously, 20% acetylcysteine immediately without waiting for positive urine test or plasma level results: initial dose of 150 mg/kg over 15 minutes, followed by continuous infusion of 50 mg/kg in 500 mL 5% glucose/dextrose over 4 hours and 100 mg/kg in 1L 5% glucose/dextrose over 16 hours; or

Oral Methionine: 2.5 g immediately followed by three further doses of 2.5 g at four hourly intervals. For a 3 year old child, 1 g methionine every four hours for four doses has been used; or

Oral Acetylcysteine 5%: 140 mg/kg as a loading dose, then 70 mg/kg every 4 hours for a total of 17 maintenance doses. If more than 10 hours have elapsed since the overdosage was taken, the antidote may be ineffective.

While you are using it

-Things you must do

Always follow your doctor's instructions carefully. If you are about to be started on any new medicine, inform your doctor and pharmacist that you are taking IKOP® Paracetamol Honey Suspension. Inform your doctor if you are currently pregnant while taking this medicine.

-Things you must not do

Do not take IKOP® Paracetamol Honey Suspension to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you.

-Things to be careful of

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness or light-headedness may worsen.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

IKOP® Paracetamol Honey Suspension may cause:

- Cutaneous hypersensitivity reactions including skin rashes, swelling Steven Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported
- Blood disorders such as thrombocytopenia and leukopenia
- Liver and kidney damage, if you take too much (overdose)- this can be fatal in severe cases

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel:03-78835550, or visiting the website portal.bpfk.gov.my (Consumer→Reporting)

Storage and Disposal of IKOP® Paracetamol Honey Suspension

-Storage

Keep IKOP® Paracetamol Honey Suspension out of reach of children.

Store below 30°C. Keep container tightly closed and protect from light.

-Disposal

Do not use IKOP® Paracetamol Honey Suspension after the expiry date which

is stated on the carton. Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Shelf Life of IKOP® Paracetamol Honey Suspension

2 years

Product Description

-What it looks like

Honey-odour tortilla brown liquid

-Ingredients

Active ingredient (w/v)

Paracetamol 250 mg/5mL

Preservatives

Sodium methylparaben 0.08 %w/v

Sodium propylparaben 0.02 %w/v

-MAL number:

MAL

Manufacturer and Product Registration Holder

IKOP® Sdn Bhd,
Jalan Sultan Ahmad Shah,
Bandar Indera Mahkota,
25150 Kuantan ,
Pahang Darul Makmur, Malaysia

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20/05/2019

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