

ACTIMOL SUSPENSION 250MG/5ML

Paracetamol (250mg/5ml)

What is in this leaflet

1. What ActiMol Suspension is used for
2. How ActiMol Suspension works
3. Before you use ActiMol Suspension
4. How to use ActiMol Suspension
5. While you are using ActiMol Suspension
6. Side effects
7. Storage and disposal of ActiMol Suspension
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What ActiMol Suspension is used for

ActiMol Suspension is used for the relief of fever including fever after vaccination, additionally to treat headache and symptoms of cold and flu. Besides that, it also reduces pain of toothache and discomfort of teething.

How ActiMol Suspension works

ActiMol Suspension works as analgesic (pain relief) and antipyretic (anti-fever) with minimal anti-inflammatory properties.

Before you use ActiMol Suspension

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

Allergy alert: Paracetamol may cause severe skin reactions. Symptom 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.

- When you must not use it

You must not take this medicine and should talk to your doctor or pharmacist if:

- You are allergic to Paracetamol or to other ingredients in it.
- You are not sure whether you should start taking this medicine.

- Before you start to use it

Tell your doctor if:

- You have allergies to Paracetamol
- You have kidney or liver problem.

ActiMol Suspension should be given with care to patients with impaired kidney or liver function. ActiMol Suspension should also be given with care to patients taking other drugs that affect the liver.

Pregnancy and lactation

This product is intended to be used in children.

Talk to your doctor or your pharmacist before taking this medicine if you are pregnant, thinking of becoming pregnant or are breastfeeding.

- Taking other medicines

Tell your doctor or pharmacist before taking ActiMol Suspension, if you are taking any other medicines, including any that you buy without a prescription from pharmacy, supermarket or health food shop. The effects of some medicines may be affected if other medicines are used at the same time.

Do not take other Paracetamol containing medicine at the same time.

Tell your doctor if you are using ActiMol Suspension in combination with the following:

- Anticoagulants (to prevent blood clot) such as warfarin and other coumarins.
- Liver enzyme inducers such as barbiturates, tricyclic antidepressants and alcohol.
- Metoclopramide or domperidone (to treat and prevent nausea and vomiting).
- Antivirals (for treating viral infections), cholestyramine (to lower high levels of cholesterol in blood).
- Anticonvulsants (to treat epileptic seizures) and oral contraceptives (birth control pill).

How to use ActiMol Suspension

Always take the medicine exactly as your doctor or pharmacist has told you, read the direction label carefully. If you have any concerns about how to take this medicine, talk to your doctor or pharmacist.

Do not exceed recommended dose.

- How much to use

Your doctor will advise you how many doses are needed each day, and for how long you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The following are the recommended dosage to use:

For an accurate dosing, weigh your child and work out the dosage to be given based on a 15 mg paracetamol for every kg body weight.

ACTIMOL SUSPENSION 250MG/5ML

Paracetamol (250mg/5ml)

For ActiMol Suspension 250mg/5ml,
Dose:

$$\frac{\text{BW (kg)} \times 15 \text{ mg} \times 5 \text{ ml}}{250 \text{ mg}}$$

Example of dose by weight:

WEIGHT (kg)	DOSE (ml)
12 – 13 kg	3 ml
14 – 16 kg	4 ml
17 – 19 kg	5 ml
20 -23 kg	6 ml
24 – 26 kg	7 ml
27 - 29 kg	8 ml
30 – 33 kg	9 ml
34 – 39 kg	10 ml
40 – 42 kg	12 ml

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.

- When to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist.

Do not take more than 4 times within 24 hours and never exceed the recommended dose unless prescribed by a doctor or pharmacist.

- How long to use it

Continue taking your medicine for as long as your doctor or pharmacist recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to take it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting unwanted side effects.

- If you use too much (overdose)

Immediately contact your doctor or go to the Emergency Department at your nearest hospital if you or anyone else has taken a large amount of this medication. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of ActiMol Suspension overdose include vomiting, stomach pain, low blood pressure, pale, and sweating. The most serious adverse effect of acute overdose of paracetamol is a dose-dependent, potentially fatal liver failure.

While you are using it

- Things you must do

Take the medication exactly as your doctor or pharmacist prescribed.

- Tell your doctor or pharmacist if you have allergies to Paracetamol.
- Tell your doctor or pharmacist what other prescription and non-prescription medicines that you are taking.
- Tell all the doctors, dentists and pharmacists treating you that you are taking ActiMol Suspension.
- Tell your doctor immediately if you become pregnant while taking this medication.
- You should contact your doctor or pharmacist if symptoms persist (if

the pain lasts for more than 10 days, if there is redness or fever that last more than 3 days).

- Things you must not do

Do not give ActiMol Suspension to anyone else, even if their symptoms or condition seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to take it.

- Things to be careful of

Do not take alcoholic beverages with ActiMol Suspension

Avoid prolonged use with high dosage.

Driving and using machines:

ActiMol Suspension has no or negligible influence on the ability to drive or use machines. If the medicine makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, ActiMol Suspension can cause side effects, although not everybody gets them. Visit the doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Ask your doctor or pharmacist to answer any questions you may have.

The side effects of ActiMol Suspension are rare and usually mild, although haematological reactions have been reported.

The significant effects are such as low platelet count, low white blood cells,

ACTIMOL SUSPENSION 250MG/5ML

Paracetamol (250mg/5ml)

low neutrophil count, low red and white blood cells as well as platelet count, produce abnormal amount of methemoglobin, severely low white blood cells and swelling beneath the skin's surface.

Meanwhile, rare side effects are low blood pressure and fast heartbeat. For side effects on stomach and intestine disorders are nausea, vomiting and constipation.

For side effect on nervous system disorders is headache. For side effect on psychiatric disorders is having trouble to sleep. For side effects on skin and subcutaneous tissue disorders are redness of the skin and itchy skin. For potentially fatal side effects are liver damage and kidney injury.

Other skin hypersensitivity reactions including skin rashes, swelling beneath the skin's surface (angioedema) and *Stevens Johnson syndrome/Toxic Epidermal Necrolysis* have also been reported.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ActiMol Suspension

- Storage

Keep out of reach of children.

Do not take this medicine beyond the expiry date imprinted on the product packaging.

Keep container tightly closed in a dry place, below 30°C. Protect from light.

- Disposal

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 environment.

Product Description

- What it looks like

An orange suspension with mentholated sweet and sour orange taste.

- Ingredients

- Active ingredient:

Each 5ml contains Paracetamol 250mg.

- Inactive ingredients:

Methylparaben, Propylparaben, Saccharin Sodium, Xanthan Gum, Sugar Granular, Glycerin, Propylene Glycol, Color FDC Yellow, Orange Flavour Sol. Sweet, Carboxymethylcellulose Sodium, Microcrystalline Cellulose, Sorbitol, Menthol Crystal, Citric Acid Monohydrate, Sodium Citrate, and Purified Water

- MAL number:

MAL20046151XZ

Manufacturer

Idaman Pharma Manufacturing Sdn Bhd (661901-P)
Lot 24 & 25, Jalan Perusahaan Lapan,
Bakar Arang Industrial Estate,

08000 Sungai Petani, Kedah Darul Aman, Malaysia.

Product Registration Holder

Idaman Pharma Manufacturing Sdn Bhd (200401023395)
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Date of revision

02/10/2023

Serial Number

NPRA (R2) 19/216