

ZORAFEN ORAL SUSPENSION

Ibuprofen (100mg/ 5ml)

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What Zorafen oral suspension is used for

For the relief of fever such as fever associated with cold and flu, and pain such as pain from teething and toothache, earache, sore throats, headache and minor aches and sprains. It is also for the relief of inflammation of muscles and joints.

How Zorafen oral suspension works

This medicine contains Ibuprofen which belongs to a group of medicines called non steroidal anti-inflammatory drugs (NSAIDs) which act to relieve of pain, fever and inflammation.

Before you use ZORAFEN

This medicine can be given to children from the age of 6 months. However, some children should not be given this medicine or you should seek the advice of their pharmacist or doctor first.

-When you must not use it

Do not give the medicine:

- If your child has or has had stomach ulceration.
- **If your child is allergic** to ibuprofen or any other ingredients in the product, aspirin or other non-steroidal anti-inflammatory medicines (your child has ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)

-Before you start to use it

Talk to your pharmacist or doctor if your child has medical condition such as:-

1. Asthma
2. Suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
3. Heart disease
4. Liver or kidney failure
5. diuretic (medicines for high blood pressure)- induced volume depletion
6. Vision problem
7. Collagen disease
8. Ulceration, bleeding and perforation of the stomach and intestinal

-Taking other medicines

If your child takes other medicines:

Before you give this medicine, make sure that you tell your pharmacist about ANY other medicines you might be giving to the child at the same time, particularly the following:

- Oral anticoagulants (medicines for blood thinning effect), for example coumarin
- Anti-hypertensive treatment (for high blood pressure), for example

thiazide diuretics, ACE inhibitors and beta-blockers

- Methotrexate a medicine used to treat rheumatoid arthritis (systemic inflammatory disorder that affects joints), as well as some types of cancers.
- Lithium, a medicine used to treat depression.
- Other pain relievers containing aspirin, ibuprofen or other NSAIDS

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for your child, including herbal and homeopathic remedies.

How to use Zorafen oral suspension

-How much to use

Shake the bottle thoroughly before use.

Age	How much	How often
6 – 12 months	2.5ml	3 to 4 times a day
1 – 3 years	5ml	3 times a day
4 – 6 years	7.5ml	3 times a day
7 – 9 years	10ml	3 times a day
10 – 12 years	15ml	3 times a day

For fever relief after vaccination:

The daily dosage of Zorafen Oral Suspension is 20-40 mg per kg body weight in divided doses. It is recommended that children weighing less than 30kg should not take more than 5 level teaspoons (500mg) within 24 hours.

Give 2.5 ml. Give a second 2.5 ml after 6 hours, if you need to. Don't give any more medicine. See your doctor if fever continues.

Do not give more than the amount recommended above.

Do not give to children under 6 months old, unless your doctor tells you to.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

If symptoms **worsen** at any time, talk to your doctor.

If symptoms do not go away within 3 days, talk to your doctor.

-If you forget to use it

If your child are taking Zorafen oral suspension on a regular basis, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

-If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much Zorafen oral suspension may cause nausea, abdominal pain and vomiting, dizziness and rarely loss of consciousness.

While you are using Zorafen oral suspension

-Things you must do

If your child are about to be started on any new medicine tell your doctor and pharmacist that your child are taking Zorafen.

Tell all of the doctors, dentists, and pharmacists that are treating your child that your child are taking Zorafen.

If your child are going to have surgery, make sure the surgeon and anaesthetist know your child are taking Zorafen.

Tell your doctor if, for any reason, your child have not taken the medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your child treatment unnecessarily.

Tell your doctor if you feel the medicine is not helping your child condition.

This will help your doctor to determine the best treatment for your child.

Be sure to keep all of your child doctor's appointments so that your child progress can be checked.

Your doctor may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

-Things you must not do

Do not take any other medicines to relieve pain and reduce inflammation while your child are

taking Zorafen without first telling your doctor. This includes:

- aspirin (also called acetylsalicylic acid)
- other medicines containing ibuprofen, the active ingredient in Zorafen
- any other NSAID medicine

Do not take Zorafen to treat any other complaints unless your doctor tells you to.

Do not give Zorafen to anyone else, even if they have the same condition as your child.

-Things to be careful of

The use of ibuprofen during pregnancy should, if possible, be avoided. ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

Pregnancy: Whilst no teratogenic effects have been demonstrated in animal experiments, the use of ibuprofen during pregnancy should, if possible, be avoided.

Breastfeeding: Talk to your pharmacist or doctor before you take this medicine.

Side effects

Like all medicines, Zorafen oral suspension can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if your child experience any side effects after taking this medicine. See a doctor at once:

- Your child has stomachache and it contains blood or dark particles that look like coffee grounds
- Pass blood in their stools or pass black tarry stools
- Allergic reactions such as skin rash (which can sometimes be severe and include peeling and

blistering of the skin), swelling of the face, neck or throat, worsening of asthma, difficulty in breathing

- Nausea
- Stomach and intestinal intolerance
- Liver and kidney problem
- Headache
- Dizziness
- Hearing disturbance
- Easy bruising

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

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 (Consumers → Reporting)

Storage and Disposal of ZORAFEN

-Storage

Store below 30°C.

Protect from light.

Keep this medicine in a safe place out of reach of children, preferably in a locked cupboard.

-Disposal

Dispose the medicine after the expiry date.

Consult your pharmacist on how to safely dispose of any medicines no longer required.

Product description

-What it looks like

An opaque orange viscous liquid with orange flavour.

-Ingredients

Active ingredient:

Each 5 ml contains Ibuprofen 100 mg.

Inactive ingredient:

Sodium Benzoate, Sorbitol Solution 70%, Xanthan Gum, Glycerin, Polysorbate 80, Sodium Citrate, Citric Acid Anhydrous, Sunset Yellow FCF, Monoammonium Glycyrhizinate, Sucralose, Orange Flavour, Sodium Chloride and Purified Water.

MAL number: MAL13035050AZ

Manufacturer:

HOE Pharmaceuticals Sdn. Bhd.
Lot 10, Jalan Sultan Mohd. 6,
Bandar Sultan Suleiman,
42000 Port Klang, Selangor,
MALAYSIA.

Product Registration Holder:

HOE Pharmaceuticals Sdn. Bhd.
Lot 10, Jalan Sultan Mohd. 6,
Bandar Sultan Suleiman,
42000 Port Klang, Selangor,
MALAYSIA.

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