

PRUFEN ORAL SUSPENSION

Ibuprofen (100mg/5ml)

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What Prufen Oral Suspension is used for

Ibuprofen is the active ingredient of Prufen Oral Suspension. It is indicated for the relief of fever and pain the children older than 6 months and control of symptoms associated with juvenile arthritis (inflammation of the synovium in children aged 16 or younger) and dysmenorrhoea (painful menstruation).

How Prufen Oral Suspension works

Ibuprofen is a non-steroidal anti-inflammatory agent that possesses analgesic (relieve pain), antipyretic (reduce fever) and anti-inflammatory activities. The mode of action, like that of other NSAIDs may be related to prostaglandin synthetase inhibition (prevent production of prostaglandin).

Before you use Prufen Oral Suspension

When you must not use it

- If you are allergic (hypersensitive) to ibuprofen and other ingredients of the oral suspension.
- If you are sensitive to aspirin or other NSAID drugs i.e if you develop bronchospasm

(constriction of the airway), angiodema (swelling of your skin), nasal polyps or urticaria (itching or hives) with those drugs or with a history of bronchial asthma.

- If you have stomach and intestinal bleeding or in the presence of peptic ulceration.
- If you are pregnant or a nursing mother

Before you start to use it

You must tell your doctor if:

- You have allergies to any medicine which you have taken previously to treat your current condition.
- You are pregnant, trying to become pregnant or breast-feeding.
- You have bleeding disorders.
- You have kidney, heart or liver problem.
- You have or have had ulceration, bleeding and perforation of the stomach and intestinal.
- Vision problem.
- Suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
- You are drinking alcohol.
- You are smoking.
- You are taking steroid.
- You are elderly or debilitated patient.

Taking other medicines

The following drug may interact with Prufen Oral Suspension:

- ACE inhibitors, medicines for high blood pressure.
- Cyclosporin, medicine used for organ transplant.
- Lithium, medicine for depression.

- Methotrexate, a medicine used to treat rheumatoid.
- 4-Quinolone antibacterial, medicines for infection.
- Sulphonylureas, medicines for diabetes.
- Coumarin anticoagulants, medicines used to prevent heart attacks, stroke and blood clots in veins and arteries, combining the two medications may increase the risk of bleeding.

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription.

How to use Prufen Oral Suspension

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to use

Fever: Children 6 months to 12 years old: 5-10mg/kg body weight up to maximum of daily dose 40mg/kg daily for temperature below or above 39°C, respectively. This can be achieved as follows:

6 months-2 years: 2.5ml three to four times a day
 3-7 years: 5ml three to four times a day
 8-12 years: 10ml three to four times a day

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue taking Prufen Oral Suspension for as long as your doctor recommends.

Take this medicine only by mouth. It may be given with food or milk to reduce gastro-

intestinal (stomach and intestinal) disturbances.

- *If you forget to use it*

- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

- *If you use 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.

Symptoms of over dosage may include:

- Abdominal pain
- Nausea
- Vomiting
- Lethargy (sleepiness) and drowsiness
- Nystagmus (fast eye movement that you cannot control)
- Apnea (slow breathing or short period of time without breathing)
- Cyanosis (blue color around the lips, mouth and nose.)
- Response only to painful stimuli.

While you are using it

- *Things you must do*

Contact your doctor if your symptoms worsen or they do not improve.

If you do become pregnant whilst taking Prufen Oral Suspension, tell your doctor.

- *Things you must not do*

Do not give Prufen Oral Suspension to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Prufen Oral Suspension for you and your condition.

- *Things to be careful of*

- Ibuprofen should be given with care to patients with bleeding disorders, cardiovascular disease, impaired liver function or a history of liver disease, impaired renal function, peptic ulceration or a history of such ulceration and in those who are receiving coumarin anticoagulants.
- Ibuprofen should be discontinued in patients who experience blurred or diminished vision, or changes in color vision.
- Safety and efficacy of ibuprofen in children younger than 6 months of age have not been fully established. It should not be used as self-medication in children younger than 12 years unless under medical supervision.

Risk of GI Ulceration, Bleeding and Perforation with NSAID.

Serious stomach and intestinal toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms.

Although minor upper GI problems (e.g dyspepsia) are common, usually developing early in the therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.

Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

Side effects

Like all medicines, Prufen Oral Suspension can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

Most frequent: gastro-intestinal (stomach and intestine) disturbances, peptic ulceration (an ulcer in the lining of the stomach, duodenum, or esophagus) and stomach and intestinal bleeding.

Others: headache, dizziness, nervousness, skin rash, pruritus (severe itching of the skin), tinnitus (ringing in the ears), oedema (swelling), depression, drowsiness, insomnia and blurred vision and other ocular reactions.

Hypersensitivity reactions, abnormalities of the liver function test, impairment of renal (kidney) function, agranulocytosis (decrease of white blood cell) and thrombocytopenia (low blood platelet count) have occasionally been observed.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Consult your doctor or pharmacist if you are in doubt or for any further information.

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 Prufen Oral Suspension

- Storage
Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Prufen Oral Suspension should be stored in well-closed container at a cool dry place; below 25°C

Keep out of the reach and sight of children.

- 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 the environment.

Product Description

- What it looks like
An orange coloured suspension with tutti frutti flavour and sweet sour taste.

They are filled in 60ml plastic bottle.

- Ingredients
 - Active ingredient
Each 5ml of suspension contains Ibuprofen 100mg.

Inactive ingredients

Other ingredients includes Sorbitol Suspension 70%, Polysorbate 80, Sucrose Suspension Grade, Citric Acid Hydrous, Sodium Citrate, Sodium benzoate, Xanthan Gum, Colloidal Silicone Dioxide, Tutti Frutti Flavour and Sunset Yellow FCF.

- MAL number
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Manufacturer and Product Registration Holder

Malaysian Pharmaceutical Industries Sdn. Bhd.
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