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NUROFEN FOR CHILDREN

Ibuprofen 100mg/5mL

PLEASE READ ENTIRE LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE. Keep this leaflet. You may want to read it again.

WHAT IS IN THE PACK?

The bottle contains a pleasant orange flavoured Nurofen For Children. Each 5mL of syrup contains the active ingredient Ibuprofen B.P 100mg. Comes in pack sizes of 60mL.

Also contains: Methylhydroxybenzoate, Propylhydrozybenzoate, Refined Sugar, Citric Acid Monohydrate, Sodium Benzoate, Agar Powder, Glycerin, Sorbitol Solutions, Sodium Saccharin, Irradiated Light Kaolin, Tween 80, Sunset Yellow FC, Orange Flavour, Purified Water.

Manufactured by:

Reckitt Benckiser Healthcare Manufacturing (Thailand) Ltd. 65 Moo 12, Lardkrabang-Bangplee Road, Bangplee, Samutprakarn 10540, Thailand.

Imported by: Reckitt Benckiser (Singapore) Pte. Ltd.

- 12 Marina Boulevard #19 01.
- Marina Bay Financial Centre.
- Tower 3, Singapore 018982

Product Licence No.: SIN11880P

HOW DOES NUROFEN FOR CHILDREN WORK?

Nurofen For Children provides relief by changing the body's response to high temperature, pain and swelling. The active ingredient of Nurofen For Children is ibuprofen and it belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). It acts by targeting the site of fever & pain.

Nurofen For Children is suitable for most babies and children from 6 months, to be given orally. Nurofen For Children is indicated for the reduction of fever (including that associated with immunization), and the relief of pain from teething, toothache, earache, sore throats, minor aches and sprains. Your doctor may prescribe this medicine for other conditions; follow his/her instruction on how often and how much to give your child.

CHECK BEFORE YOU TAKE THIS PRODUCT:

- Nurofen For Children should not be given to your baby or child if:
- They experience symptoms of dengue fever (e.g. high fever, severe headache, muscle and joint pains)
- They had an allergic reaction to aspirin, ibuprofen, other NSAID medicine or any of the ingredients listed above.
- They are taking other NSAID pain killers (e.g. ibuprofen, naproxen, diclofenac), or aspirin with a daily dose above 75mg.
- They have had a worsening of asthma, allergic rash or an itchy, runny nose when taking ibuprofen, aspirin or other NSAID medicines.
- They have or have ever had a stomach ulcer, perforation or bleeding.
- They have severe kidney, heart or liver failure.
- They weigh less than 5kg or are under 6 months of age.
- Ask your doctor before giving Nurofen For Children to your baby or child if:
- They have asthma or have suffered from asthma.
- They have kidney, heart, liver or bowel problems.
- They have condition which may put them at risk of heart problems, such as diabetes or high cholesterol.
- They are dehydrated as there is a risk of renal impairment.
- They have or have had history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease).
- They have or have had Systemic Lupus Erythematosus (SLE) and mixed connective tissue disease
- They are taking any regular medication, especially:
- Other pain relievers or products containing aspirins, ibuprofen or other NSAIDs
- Medicines for high blood pressure, e.g. water tablets (diuretics)
- Medicines for thinning the blood (anti-coagulants)
- Methotrexate or Lithium

· They are having chickenpox (varicella).

The above information also applies to adults who may wish to take Nurofen For Children. The use of ibuprofen during pregnancy should, if possible, be avoided.

HOW SHOULD NUROFEN FOR CHILDREN BE GIVEN?

READ THE LEAFLET CAREFULLY BEFORE USE. Shake the bottle well before measuring the dose. Do not give to babies under 6 months or babies weighing less than 5kg. For post-immunisation fever: Can be given to babies from 6 months old on the advice of the doctor. Initial dose of 2.5mL followed by a further 2.5mL 6 hours later if necessary. No more than 5.0mL in 24 hours. If the fever is not reduced, consult your doctor.

For pain and fever: The daily dosage of Nurofen For Children is 20-30mg/kg body weight in divided doses to be taken with or after food:

Babies 6-12 months: 2.5mL may be taken three to four times daily in 24 hours.

Children 1-3 years: 5.0mL may be taken three times daily in 24 hours. Children 4-6 years: 7.5mL may be taken three times daily in 24 hours.

Children 7-9 years: 10.0mL may be taken three times daily in 24 hours. Children 10-12 years: 15.0mL may be taken three times daily in 24 hours.

1 teaspoon = 5.0mL. Do not exceed the stated dose. Doses should be given every 6-8 hours as necessary or with a minimum of 4 hours if recommended by doctor.

For short-term use only. If the child's (aged 6 months and over) symptoms persist for more than 3 days, consult your doctor. For children under 6 months, medical advice should be sought.

WHAT TO DO IF YOU GIVE TOO MUCH? Problems in overdose are rare, but if you accidentally give more than the recommended dose, contact your doctor straight away. If you forget a dose, give the next dose when needed, provided that the last dose was taken at least 4 hours ago. Do not give a double dose.

WHILST TAKING NUROFEN FOR CHILDREN:

Side effects:

The most common side effect is irritation of the stomach which can cause problems such as indigestion and

If your baby or child experiences any of the following, or has any other unusual symptoms, stop giving this medicine and consult your doctor immediately

- Blood in the stools (faeces/motions)
- Black tarry stools
- Vomiting blood or dark particles that look like coffee grounds
- Unexplained wheezing, shortness of breath, skin rash (which may be severe with blistering or peeling of the skin), itching or bruising, racing heart, fluid retention (swollen ankles or decreased levels of passing urine).
- Stiff neck, headache, nausea, vomiting, fever and disorientation.
- Unexplained stomach pain, indigestion, heartburn, nausea or vomiting
- Yellowing of the eyes, pale stools and dark urine
- Severe sore throat with high fever
- Unexplained bruising or tiredness or getting more infections, such as colds, than normal.

Other side effects which may occur are:

- Uncommon
- Headache
- Diarrhoea, wind or constipation. Tell your doctor if these last for more than a few days or become troublesome.

Very rare:

- Kidney problems may occur with ibuprofen.
- Ibuprofen may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses (2400mg daily) or prolong treatment. This is unlikely at the dose level given to children.
- · High blood pressure
- Worsening of colitis and Crohn's disease.

STORAGE

- Store below 30°C.
- Use by the date shown on the label or carton.

KEEP ALL MEDICINES OUT OF SIGHT AND REACH OF CHILDREN

Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby.

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