

NUROFEN[®] FOR CHILDREN 3 months to 9 years

orange
Ibuprofen



Ibuprofen 100mg/5ml

Read all of this leaflet carefully before you use this medicine.

Keep this leaflet: you might need it again.

► WHAT IS IN THE PACK?

The bottle contains 100 ml of Nurofen For Children 3 months to 9 years Orange.

Each pack contains a dosing syringe.

CE 0543

The CE mark only covers the dosing syringe.

Each 5ml of oral suspension contains the active ingredient Ibuprofen 100 mg.

Also contains: Maltitol Liquid, Water, Glycerol, Citric Acid, Sodium Citrate, Sodium Chloride, Sodium Saccharin, Orange Flavour, Xanthan Gum, Polysorbate 80, Domiphen Bromide.

Licence Holder:

Crookes Healthcare Limited, Nottingham, NG2 3AA

Syringe Manufacturer:

Crookes Healthcare Limited, Nottingham NG2 3AA

Manufacturer of the medicine:

BCM Ltd, Nottingham NG2 3AA

100ml: PL00327/0158

► HOW DOES IT WORK?

Nurofen For Children 3 months to 9 years Orange contains the active ingredient ibuprofen, which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to high temperature, pain and swelling.

► WHAT IS IT FOR?

Nurofen For Children 3 months to 9 years Orange is made for babies and children from 3 months. It is given by mouth to:

- provide fast, effective reduction in your child's temperature
- relieve pain from teething and toothache, sore throats, headache and minor aches and sprains.

► CHECK BEFORE YOU GIVE/TAKE THIS PRODUCT

Do not give to babies or children who:

- are under 3 months old or weigh less than 5kg
- have or have ever had a stomach ulcer, or perforation or bleeding of the stomach
- are allergic to any of the ingredients or to aspirin or to other painkillers
- suffer from severe liver, kidney or heart problems
- are taking other NSAID painkillers
- have inherited problems coping with fructose/fruit sugar (hereditary fructose intolerance).
This is because the body can make some fructose from the ingredient Maltitol.

Talk to your doctor before giving your child this medicine if they:

- have asthma or have suffered from asthma
- have kidney, heart, liver or bowel problems
- have Systemic Lupus Erythematosus (SLE)
 - a condition of the immune system affecting connective tissue resulting in joint pains, skin changes and disorder of other organs
- are taking any regular medication, especially:
 - low dose aspirin (up to 75mg daily)
 - medicines for high blood pressure and water tablets (diuretics)
 - medicines for thinning the blood (anti-coagulants)
 - corticosteroids
 - Methotrexate
 - Lithium (used to treat depression)
 - Zidovudine (an anti-viral drug)

Some people may react badly to certain ingredients, such as maltitol and glycerin (also known as glycerol) because:

- Maltitol may have a mild laxative effect.
- Glycerol may cause headache, stomach ache or diarrhoea.
- Medicines such as Nurofen For Children 3 months to 9 years Orange, may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or take for longer than necessary to control the symptoms.
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

If adults take this medicine:

In addition to warnings and information above the following apply:

- Do not take ibuprofen if you are in the last 3 months of pregnancy.
- Do not take ibuprofen if you are taking other NSAID painkillers, or aspirin with a daily dose above 75mg.
- Ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is



unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.

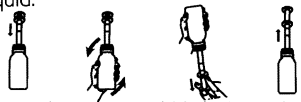
- You should only take this product on doctors advice if you are in the first 6 months of pregnancy or breast-feeding.

▶ HOW TO USE THIS MEDICINE?

Remove the cap (push it down and turn it anti-clockwise).

Using the 5ml easy dosing syringe:

- 1 Push the syringe firmly into the plug (hole) in the neck of the bottle.
- 2 Shake the bottle well.
- 3 To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the liquid to the correct mark on the syringe.
- 4 Turn the bottle the right way up and remove the syringe from the plug and bottle by gently twisting the syringe.
- 5 Place the end of the syringe into the child's mouth. Press the plunger slowly down to gently release the liquid.



After use replace the cap. Wash the syringe in warm water and allow to dry. Store out of the reach of children.

How much medicine to use?

■ For Post-Immisation Fever:

One 2.5ml dose followed by one further 2.5ml dose 6 hours later if necessary.

No more than two 2.5ml doses in 24 hours.

If the fever is not reduced, consult your doctor.

Not suitable for children under 3 months of age.

■ For Pain and Fever Relief:

This medicine is for short term use only.

Do not give to babies aged 3 to 6 months for longer than 24 hours.

Do not give to children over 6 months for longer than 3 days.

If symptoms persist or worsen, consult your doctor.

- **Babies 3-6 months weighing more than 5kg:**
Give 2.5ml three times in 24 hours.
- **Babies 6-12 months:**
Give 2.5ml three to four times in 24 hours.
 - **Children 1-3 years:**
Give 5ml three times in 24 hours.
 - **Children 4-6 years:**
Give 7.5ml (5ml + 2.5ml) three times in 24 hours.
 - **Children 7-9 years:**
Give 10ml three times in 24 hours.

Doses should be given approximately

every 6 to 8 hours if required, with a minimum of 4 hours between each dose.

DO NOT EXCEED THE STATED DOSE

▶ WHAT TO DO IF YOU GIVE TOO MUCH

If you accidentally give more than the recommended dose contact your doctor straight away.

▶ SIDE EFFECTS

Although side effects are uncommon, your child may get one of the known side effects of NSAIDs. Possible side effects include:

- Allergic reactions including worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face and tongue, collapse. In addition, there may be skin reaction (including lumpy rash and itching); these can sometimes be severe with blistering and peeling of skin.
- Stomach and bowel problems including stomach discomfort or pain, nausea, dyspepsia, diarrhoea, flatulence (*wind*), constipation, stomach ulcer, vomiting containing either blood or brown grit (like coffee grounds), black tarry stools, worsening of existing bowel diseases (ulcerative colitis or Crohn's disease).
- Blood problems resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, very pale skin or weakness.
- Liver problems that may be indicated by yellowing of the skin and eyes and/or pale stools and dark urine.
- Kidney problems that may be indicated by passing less or more urine than normal, cloudy urine, blood in the urine, pain in the back and/or swelling (particularly of the legs).
- Immune system problems associated with SLE indicated by severe headaches, neck stiffness, feeling confused or disorientated or light hurting the eyes.
- Medicines such as Nurofen For Children 3 months to 9 years Orange, may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

If you experience any of these, or have any other unusual symptoms or concerns, stop giving or taking the product immediately and see your doctor as soon as possible. Elderly people using the product are at increased risk of developing problems associated with side effects.

▶ STORAGE

Do not store above 25°C.

Use by the date shown on the label and carton.

Remember: Keep all medicines out of the reach and sight of children.

▶ HOW CAN YOU OBTAIN MORE INFORMATION ABOUT THIS MEDICINE?

This leaflet gives you the most important patient information about Nurofen For Children 3 months to 9 years Orange. If you have any questions after you have read it, ask your doctor or pharmacist, who will give you further information.

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Crookes Healthcare Ltd, Nottingham, NG2 3AA.