

NUROFEN[®]

FOR CHILDREN

strawberry

Ibuprofen



Ibuprofen 100mg/5ml

PLEASE READ ALL OF THIS 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 either 150 ml or 200 ml of Nurofen For Children Strawberry. Each pack contains a syringe

CE 0543

The CE mark only covers the syringe.

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

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

Licence Holder:

Crookes Healthcare Limited, Nottingham
NG2 3AA.

PL 00327/0156



Manufacturer of the syringe: Crookes Healthcare Ltd.
Nottingham NG2 3AA;

Manufacturer of the medicine: BCM Ltd.
Nottingham NG2 3AA

► HOW DOES NUROFEN FOR CHILDREN STRAWBERRY WORK?

Nurofen For Children Strawberry provides relief by changing the body's response to high temperature, pain and swelling.

Nurofen For Children Strawberry contains the active ingredient ibuprofen, which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). It acts by targeting the source of fever and pain.

► WHAT IS IT FOR?

Nurofen For Children Strawberry is specially formulated for babies and children from 3 months. It is given by mouth to:

- provide fast, effective and long lasting reduction in your child's temperature (including fever caused by immunisation)
- soothes away pain from teething and toothache, earache, sore throats, headache and minor aches and sprains.

Your doctor may prescribe this medicine for other

conditions. Follow his/her instructions on how often and how much to give your child.

► 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.

Adults taking this product should be aware of these factors and additionally not take the product if you:

- are taking other NSAID painkillers, or aspirin with a daily dose above 75mg
- are in the last 3 months of pregnancy.

Talk to your doctor before giving Nurofen For Children Strawberry if they/you

- have asthma or have suffered from asthma
- have kidney, heart, or liver or bowel problems
- have Systemic Lupus Erythematosus (SLE) – a condition to the immune system affecting connective tissue resulting in joint pains, skin changes and disorder of other organs
- are taking any regular medication, especially:
 - if you are on 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)
- are in the first 6 months of pregnancy or breast-feeding.
- Nurofen For Children Strawberry belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that Nurofen For Children Strawberry, used occasionally, will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.

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

- Maltitol may have a mild laxative effect.
- Glycerol may cause headache, stomach ache or diarrhoea.
- Medicines such as Nurofen For Children Strawberry 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.

► HOW SHOULD NUROFEN FOR CHILDREN STRAWBERRY BE GIVEN?

Read the leaflet carefully before use.

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.

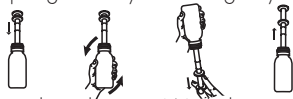
2 Shake the bottle well.

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.

■ Fever caused by Immunisation:

Only give this product to a baby under 3 months old if your doctor tells you to.

- Give 2.5ml. If necessary, give a further 2.5ml 6 hours later.
- Do not give more than 5ml in 24 hours.

If the fever is not reduced, **do not give a third dose - consult your doctor.**

■ Fever and Pain:

This medicine is for short term use only.

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

Do not give to children aged 6 months and older for more than 3 days.

Talk to your doctor promptly if your child's symptoms persist for longer than these times or if you are concerned.

- **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.

- **Children 10-12 years:** Give 15ml three times in 24 hours.

The doses should be given approximately every 6 to 8 hours, (or with a minimum of 4 hours between each dose if required).

WARNING: 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. If they do, or if you have concerns, stop giving this medicine to your child and talk to your doctor as soon as possible. Elderly people using the product are at increased risk of developing problems associated with side effects.

Disorders of the stomach and bowel including abdominal 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 disorders resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, extreme pallor or weakness.

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 hives and itching): these can sometimes be severe with blistering and peeling of skin.

Liver disorders that may be indicated by yellowing of the skin and eyes and/or pale stools and dark urine.

Kidney disorders 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).

Nervous system disorders indicated by severe headaches, neck stiffness, disorientation, and light hurting the eyes.

Medicines such as Nurofen For Children Strawberry 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 taking the product immediately and see your doctor.

► 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 NUROFEN FOR CHILDREN STRAWBERRY?

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

Date of revision April 2007