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Package Leaflet: Information for the user

NUROFEN®

Nurofen for Children Orange

3 months to 12 years

Nurofen for Children Strawberry

3 months to 12 years

100 mg / 5 ml Oral Suspension

Contains Ibuprofen

This leaflet is valid for Nurofen for Children Orange 3 months to 12 years or for Nurofen for Children Strawberry 3 months to 12 years which will be referred to as this medicine throughout this leaflet.

The only difference between both products is the flavour. To know the flavour of the medicine you are using, please refer to the carton or label.

Read all of this leaflet carefully before you use this medicine, because it contains important information for you.

Keep this leaflet: you might need it again.

Ask your doctor or pharmacist if you need more information or advice.

- This medicine is designed to help bring down a high temperature (fever and post-immunisation fever), relieve the symptoms of cold and flu and relieve pain from headaches, sore throats, ear ache, minor aches and sprains, teething and toothache.
- This medicine is suitable for most babies over 3 months of age, children and adults.
- Follow the dose instructions carefully. Section 3 shows the different amount that children need.
- Speak to your doctor if your child:
 - suffers from any of the conditions listed in section 2 of the leaflet
 - is taking aspirin at a dose above 75 mg a day. See section 2
 - is taking other medicines. See section 2.
 - is not getting better, or feeling worse, or you feel at all concerned. See section 3
 - develops a rash, breathing problems or diarrhoea and gets very tired. See section 3.
 - gets any side effects. See section 4. This includes any possible side effects not listed in this leaflet.

- Do not use this medicine and speak to your doctor if you are pregnant, think you may be pregnant or trying to get pregnant or are breast feeding. See Section 2.

In this leaflet:

- What this medicine is and what it is used for
- What you need to know before giving this medicine to your child
- How to use this medicine
- Possible side effects
- How to store this medicine
- Contents of pack and other information

1. What this medicine is and what it is used for

The active ingredient (which makes this medicine work) is ibuprofen which is a non-steroidal-anti-inflammatory (NSAID) painkiller. Ibuprofen is used as an analgesic (painkiller) for the relief of symptoms of cold and flu and mild to moderate pain, such as a sore throat, teething pain, toothache, ear ache, headache, minor aches and sprains.

This medicine also brings down a high temperature (fever) including fever caused by immunisation.

2. What you need to know before giving this medicine to your child

This medicine is suitable for the majority of people but certain people should not use it. Talk to your pharmacist or doctor if you are at all unsure.

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Immediately stop taking this medicine and contact your doctor or medical emergencies if you notice any of these signs.

Do not give this medicine to your child if:

- they have ever had a reaction (e.g. asthma, runny nose, rash, swelling of the face, tongue, lips or throat) after taking ibuprofen, aspirin or other non-steroidal anti-inflammatory (NSAID) medicines
- they weigh less than 5 kg or are under 3 months of age
- they are taking any other anti-inflammatory (NSAID) painkillers, or aspirin with a daily dose above 75 mg
- they have (or have had) two or more episodes of a stomach ulcer, perforation or bleeding
- they have severe kidney, heart or liver failure
- they have inherited problems coping with fructose/fruit sugar (hereditary fructose intolerance). This is because the body can make some fructose from the ingredient maltitol.
- they have a history of stomach bleeding or perforation after taking ibuprofen or other NSAIDs.

Warnings and precautions

Talk to your doctor or pharmacist if:

- your child has or has had high blood pressure, heart problems or a stroke because there is a small increased risk of heart problems with ibuprofen
- your child has a condition which may put them at risk of heart problems, such as diabetes or high cholesterol
- your child has asthma or any allergic disease of the lungs
- your child has, or has had liver, kidney, heart or bowel problems
- your child is dehydrated as there is a risk of kidney problems
- your child has SLE (Systemic Lupus Erythematosus, a condition of the immune system) or any similar disease
- your child suffers from chronic inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- Your child has an infection. This medicine may hide signs of an infections such as fever and pain. It is therefore possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you give this medicine to your child while they have an infection and their symptoms of the

infection persist or worsen, consult a doctor without delay.

- During chicken pox (varicella) it is advisable to avoid use of this medicine.
- If you are taking this medicine for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Skin reactions

- Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using this medicine and seek medical attention immediately, if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and this medicine

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines, especially:

- other medicines containing ibuprofen or other NSAIDs, including those you can buy over the counter
- low dose aspirin (up to 75 mg a day)
- diuretics (to help you pass water)
- anticoagulants (blood thinning medicines e.g. warfarin)
- medicines for high blood pressure (e.g. captopril, atenolol, losartan)
- lithium (for mood disorders)
- methotrexate (for psoriasis, arthritis and types of cancer)
- zidovudine (for HIV)
- corticosteroids (an anti-inflammatory drug)
- cardiac glycosides (for heart problems)
- ciclosporin or tacrolimus (to prevent organ rejection after transplant)
- mifepristone (for termination of pregnancy)
- quinolone antibiotics (for infections)
- SSRI antidepressant drugs
- antiplatelet drugs e.g. dipyridamol, clopidogrel.

Seek the advice of your doctor or pharmacist if any of the above apply.

If you are not sure what types of medicines your child is taking, show the medicine to the doctor or pharmacist.

Other warnings

The following warnings are more likely to concern adults. In any case, consider them carefully before giving or taking this medicine.

- medicines such as this medicine 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 duration of treatment
- 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
- in limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely
- if you are elderly talk to your doctor before using this medicine.

Pregnancy, breast-feeding and fertility

- 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 a doctor's advice during the first 6 months of pregnancy
- Do not take this medicine if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take this medicine during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, this medicine can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Some of the ingredients can cause problems

- Maltitol:** This product contains maltitol. If you or your child have been told by a doctor that you or your child have an intolerance to fructose, contact your doctor before taking this medicine or giving it to your child. Maltitol may have a mild laxative effect. Calorific value 2.3 kcal/g maltitol.
- Propylene glycol** (only for Strawberry flavour): This medicine contains 11.75 mg propylene glycol in each 5 ml.
- Wheat starch** (only for Orange flavour) in this medicine contains only very low levels of gluten (from wheat starch) regarded as 'gluten-free' and is very unlikely to cause problems if you have coeliac disease. One 5 ml dosage unit contains no more than 0.225 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.
- Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use this medicine

Always use this medicine exactly as described in this leaflet, or as your doctor or pharmacist told you. Check with your doctor or pharmacist if you are not sure.

Always shake the bottle thoroughly before use.

To remove the cap, push it down and turn it anti-clockwise.

There is a 5 ml easy dosing syringe or a two-ended measuring spoon (2.5 ml

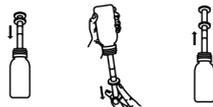
and 5 ml) in the pack which should be used to give the medicine

Using the two-ended measuring spoon

- Measure the correct dose using the 2.5 ml or 5 ml spoon ends.
- Wash and dry spoon between doses.
- Wash the spoon in warm water and allow to dry, store out of the reach of children.

Using the 5 ml easy dosing syringe

- Push the syringe firmly into the plug (hole) in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. See section 'How much medicine to use'.
- Turn the bottle the right way up, remove the syringe from the bottle plug by gently twisting the syringe.
- Place the end of the syringe into the child's mouth and gently press the plunger down to slowly and gently release the medicine.



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

How much medicine to use

DO NOT give to babies under 3 months or babies weighing less than 5 kg.

Fever caused by Immunisation

Age	Dose
Babies and children 3 months and over Weighing more than 5 kg	One 2.5 ml dose up to twice a day

If necessary the second dose should be given 6 hours after the first dose.

- Do not give more than 2 doses in a 24 hour period.
- Do not give to a child under 3 months of age, unless advised to do so by your doctor.

Fever, Pain and Symptoms of Cold and Flu

Age	Dose
3 months - 6 months Weighing over 5 kg	One 2.5 ml dose 3 times a day. Do not use for more than 24 hours

Do not give to babies aged 3-6 months for more than 24 hours. If symptoms persist after 24 hours or worsen, consult your doctor.

6 months - 12 months	One 2.5 ml dose 3 or 4 times in 24 hours
1 year - 3 years	One 5 ml dose 3 times in 24 hours
4 years - 6 years	One 7.5 ml (5 ml + 2.5 ml) dose 3 times in 24 hours
7 years - 9 years	One 10 ml (5 ml + 5 ml) dose 3 times in 24 hours
10 years - 12 years	One 15 ml (5 ml + 5 ml + 5 ml) dose 3 times in 24 hours.

Doses should be given every 6 - 8 hours.

- Leave at least 4 hours between doses.
- Do not take more than the recommended dose in 24 hours.
- For Short-term use only
- The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If your child has an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).
- Do not give to children aged 6 months or older for more than 3 days. If symptoms persist after 3 days or worsen, consult your doctor.

WARNING: Do not take more medicine than the label tells you to

For patients with sensitive stomachs the medicine can be taken with or after food.

Talk to your doctor

- If your child's symptoms do not go away as soon as possible or worsen.
- If you are not sure of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness, speak to your doctor straight away.

If you have given more this medicine than you should:

If someone has taken more medicine than they should, or if children have taken this medicine by accident, always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement.

At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to give the medicine

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most common side effect is irritation of the stomach which can cause problems such as indigestion and heartburn.

If your child experiences any of the following, stop giving this medicine and tell your doctor immediately:

- blood in the stools (faeces/motions)
- black tarry stools
- vomiting blood or dark particles that look like coffee grounds
- unexplained wheezing, asthma, shortness of breath
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
- stiff neck, headache, nausea, vomiting, fever and disorientation.
- face, tongue or throat swelling (these can be signs of serious allergic reactions)

- A severe skin reaction known as DRESS (Drug reaction with eosinophilia and systemic symptoms) syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency not known). See section 2.

Like all medicines, this medicine can cause side-effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:

- Liver, kidney problems or difficulty urinating

This medicine, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

If your child experiences any of the following side effects, stop giving this medicine and tell your doctor

- unexplained stomach pain, indigestion, heartburn, nausea or vomiting
- yellowing of the eyes, pale stools and dark urine (these can be signs of kidney or liver problems)
- severe sore throat with high fever
- unexplained bruising or bleeding, tiredness, getting more infections than normal, such as mouth ulcers, colds, sore throat, fever. (These can be signs of anaemia or other blood disorders.)

Other side effects which may occur are:

- Uncommon: may affect up to 1 in 100 people
 - headache
- Rare: may affect up to 1 in 1,000 people
 - diarrhoea, wind or constipation. Tell your doctor if these last for more than a few days or become troublesome

Very rare: may affect up to 1 in 10,000 people

- kidney or liver problems may occur with ibuprofen
- stroke or heart problems may occur with ibuprofen. This is unlikely at the dose level given to children
- worsening of colitis and Crohn's disease
- high blood pressure.
- stomach ulcer, bleeding of the stomach, inflammation of the stomach lining.

Not known: frequency cannot be estimated from the available data:

- in exceptional cases, serious infections of the skin and soft tissues have occurred during chicken pox (varicella)
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- skin becomes sensitive to light

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store this medicine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and carton. (The expiry date refers to the last day of that month.)

Store below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of pack and other information

What this medicine contains

The active ingredient is ibuprofen 100 mg per 5 ml.

The other ingredients are:

Maltitol liquid, water, glycerol, citric acid, sodium citrate, sodium chloride, sodium saccharin, orange flavour (containing wheat starch (containing gluten)) or strawberry flavour (containing propylene glycol), xanthan gum, polysorbate 80, damphen bromide.

What this medicine looks like and contents of the pack

This medicine is an off-white liquid available in 200 ml, 150 ml and 100 ml bottles. Not all pack sizes will be marketed. Each pack contains a dosing device: a two-ended spoon or a syringe.

Product licence holder: Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ

Manufacturer of medicine: Reckitt Benckiser Healthcare UK Ltd, Hull, HU8 7DS

Product licence numbers: PL 00063/0665: Nurofen for Children Orange 3 months to 12 years

PL 00063/0666: Nurofen for Children Strawberry 3 months to 12 years

This leaflet was revised: March 2024

The leaflet gives you the most important information. If you have any questions after you have read it, ask your doctor or pharmacist who will be able to help.

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CUSTOMER INFO

Minimum Point Size = 9.00pt

RB Artwork and Print Specification

Trident Reference No:	RB63814
ZEN Ref:	TR334080
Brand/Work Ref:	RBL2409968
Action:	A
Brand:	Nurofen
Category:	Paediatric
Segment Group:	Suspension 2 Percent
Segment:	Ibuprofen Orange and Strawberry
Pack Size:	200 ml
Market/Country:	UK
Date:	15/11/2024

RBH Contact: Rachel Berefordward

Artwork Type: BW Submission

Component Code (20+ applicable):	000000
2-Component Code (if applicable):	N/A
Parent Technical Packaging Specification:	D0349823
Finished Goods Code:	0000000
Supply Point:	RB Hull
3rd Party Code:	N/A
Pharmacoed No/NE:	N/A
Edgemark Position:	N/A

CAD Cam Ref: N-UK-SE-00349823-400x148mm

Printer: Generic RB

Substrate: Paper White

Technical & Non Printing Items

Dieline	Dieline 2 (if applicable)
Guides	Guides 2 (if applicable)

Colours

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Front	

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