

Junior Ibuprofen Suspension 100mg/5ml

Patient Information Leaflet

Read this leaflet carefully because it contains important information.

This medicine is available without prescription for you to treat a mild illness in your child without a doctor's help. Nevertheless, you still need to use this medicine carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or pharmacist if your child's symptoms worsen or do not improve.

In this leaflet:

- 1. What this medicine is for**
- 2. Before you give this medicine**
- 3. How to give the medicine**
- 4. Possible side effects**
- 5. Storing the medicine**
- 6. Further information**

1. WHAT THIS MEDICINE IS FOR

Junior Ibuprofen Suspension contains ibuprofen, which belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by changing how the body responds to pain, swelling and high temperature.

This medicine is used to relieve:

- Fever (high temperature) including post immunisation fever at 2 months
- Mild to moderate pain including headache, sore throat, teething pain and toothache, cold and flu symptoms and minor aches and sprains.

2. BEFORE YOU GIVE THIS MEDICINE

Do not give Junior Ibuprofen Suspension to children who:

- have or have had a stomach ulcer, perforation or bleeding of the stomach
- are allergic to ibuprofen, to any of the ingredients (listed in section 6), or to aspirin or other painkillers (an allergic reaction may be recognised as shortness of breath, runny nose, skin rash or itching)
- have kidney or heart failure or severe liver failure
- are taking more than 75mg of aspirin a day.

Warnings and precautions

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. Stop immediately this medicine and contact immediately your doctor or medical emergencies if you notice any of these signs.

Anti-inflammatory / pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

If you are taking Junior Ibuprofen Suspension for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms 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 generalized 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.

You should discuss your child's treatment with your doctor or pharmacist before giving Junior Ibuprofen Suspension to children who:

- have or have suffered from asthma or have allergies
- have liver or kidney problems
- have stomach or bowel disorders including Crohn's disease or a condition known as ulcerative colitis
- have Systemic Lupus Erythematosus (SLE) – an illness which affects your immune system. It causes joint pains, skin changes and problems with other parts of your body.
- have heart problems including heart failure, angina (chest pain), or if they have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA")
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke.
- have chicken pox (varicella). It is advisable to avoid use of ibuprofen in children who have chicken pox.
- have an infection - please see heading "Infections" below.

Children and adolescents:

There is a risk of renal impairment in dehydrated children and adolescents.

Infections

Junior Ibuprofen Suspension may hide signs of infections such as fever and pain. It is therefore possible that Junior Ibuprofen Suspension 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 take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Other medicines and Junior Ibuprofen Suspension

You must not give this medicine if they are taking certain other medicines - see section 2 'Do not give Junior Ibuprofen Suspension to children who:'.

Junior Ibuprofen Suspension may affect or may be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- corticosteroids
- methotrexate (a medicine for cancer)
- cardiac glycosides (medicines used to treat heart failure)
- cyclosporin and tacrolimus (immunosuppressant medicines often used following organ transplants)
- mifepristone (a medicine used to terminate pregnancy – NSAIDs should not be used for 12 days after mifepristone)
- lithium (for depression or mental problems)
- zidovudine (a medicine to treat viruses)
- quinolone antibiotics (medicines used to treat bacterial infections)

Some other medicines may also affect or be affected by the treatment of Junior Ibuprofen Suspension. You should therefore always seek the advice of your doctor or pharmacist before you give Junior Ibuprofen Suspension with other medicines.

If you are an adult taking this medicine you should be aware of all the above factors and additionally you should talk to your doctor or pharmacist if you:

- are a smoker
- are elderly, as there may be an increased risk of side effects.

Pregnancy, breast-feeding and fertility

Do not take Junior Ibuprofen Suspension 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 Junior Ibuprofen Suspension 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, Junior Ibuprofen Suspension 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.

Talk to your doctor before taking Junior Ibuprofen Suspension if you breastfeeding.

Junior Ibuprofen Suspension belongs to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the medicine. It is unlikely that if you only take this ibuprofen suspension occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

Important information about some of the ingredients of this medicine

This product contains liquid maltitol (E965). If you have been told by your doctor that your child may have an intolerance to some sugars, talk to your doctor before your child takes this medicinal product. May have a mild laxative effect. Each 5ml measure contains 1.375g of liquid maltitol (equivalent to 3.2 kcal per 5ml of the medicine).

This product also contains sodium methylparahydroxybenzoate (E219) and sodium propylparahydroxybenzoate (E217). These ingredients may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per 10ml, that is to say essentially 'sodium-free'.

3. HOW TO GIVE THE MEDICINE

Check the seal is not broken or the sachet is intact before first use. Shake thoroughly or massage the sachet to mix the contents. Give this medicine using the measuring spoon provided. For oral use. Do not give to a child weighing less than 5kg. Children's Ibuprofen 100mg/5mL Oral Suspension can cause a burning sensation, tingling or numbness in the mouth or throat for a short time after taking the medicine. A drink of water taken soon after the medicine is swallowed may help to reduce these effects. Babies under 6 months can be given boiled, cooled water from a baby bottle. Older children can have water from a baby bottle, top cup or open-top beaker as appropriate to the child's age.

Age	Dose
Children over 7 years:	Two 5ml spoonfuls to be given 3 times a day.
Children 4 to 7 years:	One 5ml spoonful plus one 2.5ml spoonful to be given 3 times a day.
Children 1 to 4 years:	One 5ml spoonful to be given 3 times a day.
Infants 6 months to 1 year:	One 2.5ml spoonful to be given 3-4 times a day.
If your child's symptoms persist for more than 3 days, or if new symptoms occur, talk to your doctor.	
Babies 3 to 6 months:	One 2.5ml spoonful to be given 3 times a day.
Do not give to babies aged 3 to 6 months for more than 24 hours.	
Doses should usually be given every 6 – 8 hours, preferably with or after food. Do not give more often than every 4 hours. Do not exceed 4 doses in any 24 hour period.	
Do not give to children under 3 months except for post-immunisation fever: one 2.5ml spoonful may be given followed by one further 2.5ml spoonful 6 hours later if necessary. No more than 2 doses should be given in 24 hours. If fever is not reduced, talk to your doctor.	
For short-term use only. DO NOT EXCEED THE STATED DOSE	

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

If your child takes more Junior Ibuprofen Suspension than they should:

If your child has taken more of the suspension than you should, or if your child has 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.

4. POSSIBLE SIDE EFFECTS

Most people take Junior Ibuprofen Suspension without any problems, but it can have side effects, like all medicines. To reduce the chance of side effects, especially in the elderly, use the lowest effective dose for the shortest possible time.

If your child gets any of the following at any time during the treatment STOP GIVING, and get medical help straight away:

Allergic reactions:

The following reactions may mean you are having an allergic reaction to this medicine:

- asthma, worsening of asthma, unexplained wheezing or shortness of breath
- swelling of the face, lips, tongue and throat (causing difficulty in swallowing or breathing)
- rapid heart rate, low blood pressure, collapse.
- also, there may be skin reaction (including hives, rash and itching) – very rarely these can be severe with blistering and peeling skin
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Skin problems:

- 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]
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)

Stomach and bowel problems including:

- indigestion or heartburn
- pains in their stomach (abdomen) or other abnormal stomach problems
- pass blood in their stools or motions
- pass black tarry stools or motions
- vomit any blood or dark particles that look like coffee grounds
- worsening of bowel problems (ulcerative colitis or Crohn's disease)

Blood disorders which can cause:

- unexplained or unusual bruising or bleeding
- sore throat or mouth ulcers
- fever (high temperature)
- extreme paleness or weakness and exhaustion

Heart and circulation effects: Medicines such as Junior Ibuprofen Suspension may be associated with a small increased risk of heart attack (myocardial infarction), high blood pressure, heart failure, swelling due to fluid build-up (oedema) or stroke.

Other side effects that may occur include:

Frequency not known

- in exceptional cases, serious infections of the skin and soft tissues during chicken pox (varicella).
- Skin becomes sensitive to light.

Other stomach and intestine effects including:

- diarrhoea, flatulence, constipation and vomiting.

Mouth and throat effects: Ibuprofen liquid can cause a burning sensation, tingling or numbness in the mouth or throat for a short after taking the medicine.

Liver problems that might be indicated by yellowing of the skin and eyes (jaundice) and/or pale coloured stools and dark urine

Kidney problems that might 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) – very rarely kidney failure.

Junior Ibuprofen Suspension, 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.

Nervous system problems including headache and aseptic meningitis (which can have symptoms such as severe headache, stiff neck, disorientation, fever and eye sensitivity to light in those with existing auto-immune disorders such as lupus).

Reporting of side effects

If you or your child 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. STORING THE MEDICINE

Do not use after the expiry date shown on the pack.

Do not store above 25°C. Store in the original container.

Keep out of the sight and reach of children.

6. FURTHER INFORMATION

What is in this medicine:

The active ingredient is: Ibuprofen 100mg/5ml

The other ingredients are: Sodium Methylparahydroxybenzoate (E219), Sodium Propylparahydroxybenzoate (E217), Citric Acid Anhydrous, Saccharin Sodium, Sodium Benzoate, (E211), Dispersible Cellulose, Juicy Orange Flavour, Polysorbate 80, Liquid Maltitol (E965), Xanthan Gum, Purified Water

What this medicine looks like and contents of the pack:

Junior Ibuprofen Suspension is a white opaque smooth suspension available in sachets containing a 5ml dose which are packed into cartons containing 10 or 20 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Galpharm Healthcare Ltd, Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Manufacturer: Galpharm International Ltd., Elmhirst Park, Middle Field Road, Barnsley, South Yorkshire, S75 4LS, United Kingdom.

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