

Ibuprofen 100mg/5ml Oral Suspension

Skin reactions

Serious skin reactions have been reported in association with Ibuprofen Oral Suspension treatment. You should stop taking Ibuprofen Oral Suspension and seek medical attention immediately, if your child develops any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Aseptic meningitis (inflammation of the brain membrane without bacterial infection)

During treatment with ibuprofen, some cases of meningitis (presenting as stiff neck, headache, nausea, vomiting, fever or disorientation) have been seen. Although it is probably more likely to occur in patients with existing autoimmune disorders such as systemic lupus erythematosus or mixed connective tissue diseases, it has been reported in patients who do not have an existing long-term disease.

Other medicines and Ibuprofen Oral Suspension

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. Ibuprofen Oral Suspension may affect or be affected by some other medicines. For example:

- Other medicines containing ibuprofen or other NSAIDs, including those you can buy over the counter.
- Medicines that are anti-coagulants (i.e. thin blood/ prevent clotting e.g. aspirin, warfarin, ticlopidine).
- Antiplatelet drugs (e.g. dipyridamole, clopidogrel).
- Mifepristone (for termination of pregnancy).
- Zidovudine (for HIV infection).
- Medicines known as sulfonylureas such as glibenclamide (used to treat diabetes).
- Methotrexate (for psoriasis, arthritis and types of cancer).
- Cardiac glycosides (e.g. digoxin – used to treat particular heart problems).
- Diuretics ('water tablets').
- 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 (an anti-inflammatory drug).
- SSRI antidepressant drugs (for depression).
- Antibiotics called quinolones e.g. ciprofloxacin.
- Aminoglycoside antibiotics (for infection).
- Lithium (for mood disorders).
- Ciclosporin or tacrolimus (to prevent organ rejection after transplant).
- Cholestyramine (used to lower cholesterol).
- Voriconazole or fluconazole (types of anti-fungal drugs).
- Gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

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

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

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

Ibuprofen Oral Suspension contains maltitol liquid, sodium benzoate, sodium and benzyl alcohol

If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before using this medicinal product.

Maltitol liquid may have a mild laxative effect.

Each 5ml spoonful contains 2g of maltitol liquid. This provides 4.6kcal per 5ml spoonful.

This medicine contains 0.00075mg of benzyl alcohol in each 5ml spoonful. Benzyl alcohol may cause allergic reactions. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding, have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

This medicine contains 10.0mg of sodium benzoate in each 5ml spoonful.

This medicine contains less than 1mmol sodium (23mg) per 5ml spoonful, that is to say essentially 'sodium-free'.

If you are an adult intending to take this medicine:

- All the information in this leaflet applies to you as well. In addition:
- If you are elderly you may be more likely to have some of the possible side effects listed later in the leaflet. Talk to your doctor before taking this medicine.
- If you are a smoker, you should discuss your treatment with your doctor or pharmacist before taking Ibuprofen Oral Suspension.
- Ibuprofen Oral Suspension may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol while taking Ibuprofen Oral Suspension might make these side effects worse.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The use of Ibuprofen Oral Suspension whilst pregnant or breast-feeding should be avoided. Ibuprofen Oral Suspension should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and using machines

Since side effects such as dizziness, drowsiness and visual disturbances may be experienced, the ability to drive a car or operate machinery may be impaired.

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- The leaflet is written in terms of giving this medicine to your child, but if you are an adult who is intending to take this medicine yourself the information in this leaflet will apply to you as well.
- If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your child does not feel better or feels worse:
 - after 24 hours if your child is aged under 6 months
 - after 3 days if your child is aged over 6 months.
- The full name of this medicine is Ibuprofen 100mg/5ml Oral Suspension but within the leaflet it will be referred to as Ibuprofen Oral Suspension.

What is in this leaflet

- 1 What Ibuprofen Oral Suspension is and what it is used for
- 2 What you need to know before giving Ibuprofen Oral Suspension to your child
- 3 How to use Ibuprofen Oral Suspension
- 4 Possible side effects
- 5 How to store Ibuprofen Oral Suspension
- 6 Contents of the pack and other information

1 What Ibuprofen Oral Suspension is and what it is used for

Ibuprofen Oral Suspension contains ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which act to relieve pain, swelling (inflammation) and reduce fever.

Ibuprofen Oral Suspension is for use in children from 3 months of age who weigh more than 5 kg.

It can be used for the relief of mild to moderate pain such as sore throat, teething pain, toothache, earache, headache, minor aches and sprains. It can also be used to relieve the symptoms of colds and flu and to reduce fever, including fever after vaccination at 3 months of age.

2 What you need to know before giving Ibuprofen Oral Suspension to your child

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

Do not give this medicine to your child if they:

- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- have ever had a reaction (e.g. asthma, runny nose, rash, swelling of the face, tongue, lips or throat) after taking ibuprofen, acetylsalicylic acid (aspirin) or other non-steroidal-anti-inflammatory (NSAID) medicines
- weigh less than 5kg or are under 3 months of age
- are taking any other NSAID medicines, or aspirin with a daily dose above 75mg (aspirin should not generally be given to children under 16, but doctors may occasionally prescribe it)
- have a stomach ulcer, perforation or bleeding, or they have had one twice or more in the past
- have had perforation or a bleeding ulcer after taking a NSAID medicine (your child may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in their stools or passed black tarry stools)
- have severe kidney, heart or liver failure
- have a condition which increases their tendency to bleeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before giving Ibuprofen Oral Suspension.

This is especially important if your child:

- has asthma, a history of asthma or other allergic disease
- has or has had kidney, liver or heart problems
- is dehydrated as there is a risk of kidney problems
- has connective tissue disorders such as SLE (Systemic Lupus Erythematosus)
- suffers from chronic inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- has chickenpox or shingles
- has an infection - please see heading 'Infections' below.

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.

You should discuss your child's treatment with your doctor or pharmacist before giving Ibuprofen Oral Suspension if your child:

- has 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").
- has high blood pressure, diabetes, high cholesterol, or has a family history of heart disease or stroke.

Infections

Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen 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 the child takes this medicine while they have an infection and their symptoms of the infection persist or worsen, consult a doctor without delay.

3 How to use Ibuprofen Oral Suspension

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Always shake the bottle thoroughly before use.

Always use the syringe supplied with the pack. The syringe can be used to measure 2.5ml or 5ml by drawing the liquid to the correct mark on the syringe.

The recommended dose is:

Fever caused by immunisation		
Your child's weight (and age)	How much?	How often?
Over 5kg (3 months and over)	2.5ml	Up to twice in 24 hours*

* 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 any more medicine after second 2.5ml. See a doctor if fever continues.

Fever, Pain and Symptoms of Cold and Flu		
Your child's weight (and age)	How much?	How often in 24 hours?***
Over 5kg (3 - 6 months)	2.5ml	3 times Do not use for more than 24 hours
7 - 10kg (6 - 12 months)	2.5ml	3 or 4 times
10 - 15kg (1 - 3 years)	5ml	3 times
15 - 20kg (4 - 6 years)	7.5ml (5ml + 2.5ml)	3 times
20 - 30kg (7 - 9 years)	10ml (5ml + 5ml)	3 times
30 - 40kg (10 - 12 years)	15ml (5ml + 5ml + 5ml)	3 times

*** Doses should be given every 6 - 8 hours. Leave at least 6 hours between doses.

Do not give to a child under 3 months of age, unless advised to do so by your doctor.

For Short-term use only

- Do not give to babies aged 3-6 months for longer than 24 hours.
- Do not give to children aged 6 months or over for longer than 3 days.

Consult your doctor if symptoms worsen or persist

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 more than the amount recommended above.

Directions for using the syringe:

- Shake the bottle thoroughly before use.
- 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 (2.5ml or 5ml) on the syringe.
- Turn the bottle the right way up, and then gently twist the syringe to remove from the bottle plug.
- Place the end of the syringe into the child's mouth, normally to the side of the mouth between the gums and cheek. Press the plunger down to slowly and gently release the medicine.
- If the table above advises you to give more than 5ml of the medicine, repeat steps 2 to 5 to give your child the correct amount of medicine.

After use, replace the cap on the top of the bottle tightly. Store all medicines out of the sight and reach of children. Wash the syringe in warm water and allow to dry.

If you use more Ibuprofen Oral Suspension than you should

If you have used more Ibuprofen Oral Suspension than you should, or if a child has taken this medicine by accident, always contact a doctor or your 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, difficulty urinating, cold body feeling, and breathing problems have been reported.

If you forget to use Ibuprofen Oral Suspension

If you forget a dose, give the next dose when needed, provided that the last dose was taken at least 6 hours ago. Do not take a double dose to make up for a forgotten dose.

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If your child experiences any of the following serious side effects, stop giving this medicine and seek immediate medical help:

- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.
- Signs of intestinal bleeding such as:
 - passing blood in your faeces (stools/motions)
 - passing black tarry stools
 - vomiting any blood or dark particles that look like coffee grounds

Tell a doctor and stop giving this medicine if your child experiences:

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction).
- Loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).

- Severe spreading skin rash ('Stevens-Johnson Syndrome', 'toxic epidermal necrolysis' and 'erythema multiforme', symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness)
- A severe skin reaction known as DRESS 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).

Medicines such as Ibuprofen Oral Suspension have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

Medicines such as Ibuprofen Oral Suspension have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles.

Blood disorders such as reduction in blood cells and platelet counts – the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin.

Kidney problems such as reduced kidney function, fluid retention (oedema), inflammation of the kidney and kidney failure, liver problems such as inflammation of the liver, reduced liver function and yellowing of the eyes and/or skin (jaundice) or severe skin reactions may occur rarely with ibuprofen.

Ibuprofen Oral Suspension has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

Other side effects

Common (may affect up to 1 in 10 people):

- Feeling dizzy or tired
- Diarrhoea, wind, constipation
- Headache - if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

Uncommon (may affect up to 1 in 100 people):

- Feeling drowsy
- Feeling anxious
- Feeling a tingling sensation or 'pins and needles'
- Difficulty sleeping
- Hives
- Hearing problems
- Sneezing, blocked, itchy or runny nose (rhinitis)
- Stomach or gut ulcer, hole in the wall of the digestive tract
- Inflammation of your stomach lining
- Ringing in ears (tinnitus)
- Sensation of spinning (vertigo)
- Mouth ulcers

Rare (may affect up to 1 in 1,000 people):

- Feeling depressed or confused

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

- Inflammation of the pancreas

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

- Skin becomes sensitive to light
- 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). Stop using Ibuprofen Oral Suspension if you develop these symptoms and seek medical attention immediately. See also section 2.

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 Website:

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 Ibuprofen Oral Suspension

This medicine does not require any special storage conditions. Shelf life after first opening the bottle: 6 months. Keep this medicine out of the sight and reach of children. Shake well before use. Do not use this medicine after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Ibuprofen Oral Suspension contains

- The active substance is ibuprofen.
- 5ml of oral suspension contains 100mg of ibuprofen.
- The other ingredients are: sodium benzoate (E211), citric acid, maltitol liquid, xanthan gum, hypromellose, glycerol, sodium chloride, polysorbate 80, sodium cyclamate, acesulfame potassium, sucralose, orange flavour (Orange Juice 055604 TEU) containing flavouring components (flavouring preparations, flavouring substances, natural flavouring substances), alpha-tocopherol (E307), benzyl alcohol, vanillin, purified water.

What Ibuprofen Oral Suspension looks like and contents of the pack

Ibuprofen Oral Suspension is a white to almost white suspension with orange-vanilla flavour. Ibuprofen Oral Suspension is supplied in an amber glass bottle containing 100ml, or an amber plastic bottle containing 100ml. The bottle is closed with a child-resistant plastic screw cap. Each pack also contains a plastic oral dosing syringe.

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

Balkanpharma Troyan AD, 1, Krayrechna Str., Troyan 5600, Bulgaria

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