



Care Ibuprofen for Children Oral Suspension

(Ibuprofen 100mg/5ml)

Important information about Ibuprofen for Children

- This medicine reduces fever and relieves mild to moderate pain in infants and children between 6 months and 12 years old.
- Follow the dosage instructions carefully. Children of different ages need different amounts. See section 3.

Do not give....

- For longer than 3 days.
- To infants under 6 months old.
- To anyone who is allergic to the ingredients. See section 6.
- To anyone who is allergic to aspirin.

Talk to your doctor....

- If your child is taking or is allergic to any other painkiller.
- If your child has asthma.

Now read the rest of the leaflet before you use this medicine. It includes other information which might be especially important for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need any more information or advice.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. What the medicine is for

This medicine contains Ibuprofen, a nonsteroidal anti-inflammatory drug (NSAIDs). It has pain relieving and anti-inflammatory properties and also acts to bring down high temperature. The medicine reduces fever including high temperature caused by vaccinations. It also relieves mild to moderate pain such as headache, sore throat, teething pains and toothache, cold and flu symptoms, minor aches and sprains.

2. Before you use this medicine



Warning

Anti-inflammatory/pain-killer medicines like Ibuprofen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke, particularly when used at high doses and/or prolonged treatment. Do not exceed the recommended dose or duration of treatment (3 days). If you are taking Care Ibuprofen for Children Oral Suspension for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harms to stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

If your child has heart problems, previous stroke or you think that they might be at risk of these conditions (for example have high blood pressure, diabetes or high cholesterol) you should discuss their treatment with your doctor or pharmacist. There is a risk of renal impairment in dehydrated children.

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



Do not use the medicine if your child has....

- An **allergy** to any of the ingredients listed in section 6.
- An **allergy to aspirin**.
- A history of **breathing problems, runny nose or rashes** particularly after taking aspirin or other anti-inflammatory medicines.
- A **stomach ulcer** or a history of stomach ulcers.
- **Stomach bleeding** or perforation, related to previous NSAIDs treatment.
- Severe **heart, kidney or liver failure**.
- Or the child is **under 6 months old**.

- **Do not give** this medicine with any other NSAID painkillers or aspirin with a daily dose above 75mg.



Talk to your doctor or pharmacist if your child has....

- Had 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").
- Kidney or liver problems, as a lower dose than normal may be needed.
- A history of asthma, allergies, high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke.
- Lupus, an allergic condition which causes joint pain, skin rashes and fever.
- Bowel problems, colitis or Crohn's disease.
- Chickenpox (Varicella). It is advisable to avoid use of this medicine during chickenpox.
- have an infection – please see heading 'Infections' below.

Infections:

Care Ibuprofen for Children Oral Suspension may hide signs of 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 take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

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 Care Ibuprofen for Children Oral Suspension and seek medical attention immediately if you notice any of the

symptoms related to these serious skin reactions. If you develop 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.



Talk to your doctor or pharmacist if your child is taking....

- Aspirin or any other anti-inflammatory medicines as the risk of side effects may be increased if used with Ibuprofen.
- Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- Some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan).
- Diuretics which help remove fluids from the body.
- Antibiotics for infection.
- Steroids for inflammation.
- SSRIs for depression.
- Cardiac glycosides for heart problems.
- Methotrexate, for cancer treatment.
- Ciclosporin or tacrolimus to prevent transplant rejection.
- Mifepristone for termination of pregnancy.
- Zidovudine for the treatment of HIV and AIDS.
- Lithium for manic depression.

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



Can adults take this medicine?

This product is intended for children aged between 6 months and 12 years. If you are an adult taking this product you should be aware of all the factors and the following information:

- Do not take Care Ibuprofen for Children Oral 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 you 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, Care Ibuprofen for Children Oral 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 or pharmacist before taking if:

- You are in the first six months of pregnancy.
- You are trying to get pregnant.
- You are elderly.
- You are a smoker.

Ibuprofen may impair fertility if used when trying to become pregnant. This effect is reversed when you stop taking the medicine.

Ibuprofen appears in breast milk in small amounts, but such small amounts are unlikely to affect breast-fed infants.



Driving and using machines....

This medicine may rarely cause dizziness and headaches. If you are affected do not drive or operate machinery.



Important information about some of the ingredients

- This medicine contains Liquid maltitol (contains maltitol and sorbitol).
- This medicine contains Maltitol Liquid which may have a mild laxative effect. Calorific value 2.3Kcal/g Maltitol.

Turn over ↗

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- This medicine contains 275mg sorbitol in each 5ml dose. Sorbitol is a source of fructose. If your doctor has told you that your child has an intolerance to some sugars or if they have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before your child receives this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- Sodium Methyl Parahydroxybenzoate (E219) and Sodium Propyl Parahydroxybenzoate (E217) may cause allergic reactions (possibly delayed).
- Sodium Benzoate (E211): This medicine contains 5mg Sodium Benzoate in each 5ml dose.
- This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium-free'.

3. How to use this medicine

- Shake the bottle before each use.
- Give this medicine to your child by mouth with or after food.
- Use the spoon provided to measure 2.5ml or 5ml.



Children from 8 - 12 years

Two 5ml spoonfuls three or four times a day.

Children from 3 - 7 years

One 5ml spoonful three or four times a day.

Children from 1 - 2 years

One 2.5ml spoonful three or four times a day.

Infants from 6 - 12 months

One 2.5ml spoonful three times a day.



Children under 6 months

Do not give to children under 6 months unless your doctor tells you to.



For fever following vaccination

- One 2.5ml spoonful. Repeat after 6 hours if necessary.
- Do not give more than 2 doses in 24 hours.

- If the high temperature is not reduced see your doctor.

DO NOT EXCEED THE STATED DOSE.

If this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.



If you give too much

If you have given more of this medicine than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital straight away to get an opinion of the risk and advice on action to be taken. Take the pack with you to show which medicine your child has swallowed.

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 a dose

Give the next dose as soon as you remember.

Do not give a double dose. You can then carry on with the normal dose at the correct time.

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).

4. Possible side effects

Like all medicines, Care Ibuprofen for Children Oral Suspension can cause side effects, although not everybody gets them.

Important side effects

If you think your child has any of the following serious side effects or symptoms, **STOP TAKING** this medicine immediately and see a doctor as soon as possible.

- Fast heartbeat.

- Low blood pressure (causing light headedness).
- Severe shock.
- Unexplained wheezing or shortness of breath.
- Allergic reactions including rashes or itching, bruising, blistering or peeling and swelling of the face, lips, tongue, throat or difficulty in swallowing.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- Blood in the faeces (stools/motions).
- Pass black tarry stools.
- Vomit any blood or dark particles that look like coffee grounds.
- 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 mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using this medicine if you develop these symptoms and seek medical attention immediately. See also section 2.
- Liver, kidney problems or difficulty urinating. Care Ibuprofen for Children Oral 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.

Other possible side effects

- Feeling sick.
- Indigestion or heartburn.

- Stomach pain or other stomach problems.
- Worsening of the symptoms of asthma, inflammation of the colon and crohn's disease.
- General swelling.
- High blood pressure.
- Heart failure.

Rarely

- Headache.
- Dizziness.
- Hearing disturbance.
- Diarrhoea.
- Wind.
- Constipation.
- Being sick.

Very Rarely

- Stomach ulcers, bleeding or swelling of the stomach lining.
- Meningitis.
- Kidney damage (look for passing less or more urine than normal, cloudy urine, blood in the urine, pain in the back and/or swelling particularly of the legs).
- Liver problems (look for yellowing of the skin and eyes, pale stools/motions and dark urine).
- Blood cell disorders whose symptoms include fever, sore throat, mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding, bruising or a purple skin rash.

Not Known

- 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).
 - In exceptional cases, serious infections of the skin and soft tissues have occurred during chickenpox (varicella).
 - Skin becomes sensitive to light.
- Medicines such as Ibuprofen for Children may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

If you notice these or any other side effect not included above, stop use and tell your doctor or pharmacist. They will tell you what to do.

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. Storing this medicine

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use after the expiry date shown on the carton. The expiry date refers to the last day of that month.

Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of any unused medicine. These measures will help to protect the environment.

6. Further information

What is in the medicine

The active ingredient per 5ml is: ibuprofen 100mg.

The other ingredients are:

sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate(E217), citric acid anhydrous(E330), saccharin sodium(E954), sodium benzoate (E211), dispersible cellulose, juicy orange flavour, polysorbate 80 (E433), maltitol liquid (which contains maltitol and sorbitol), xanthan gum (E415) and purified water.

What the medicine looks like

Ibuprofen for Children is a white cloudy suspension. It is supplied in 100ml bottles.

Marketing authorisation holder and manufacturer

Thornton and Ross Ltd., Huddersfield, HD7 5QH, UK.

This leaflet was last revised in December 2023