



## Information for the user

# Ibuprofen 3 Months Plus 100 mg/5 ml Oral Suspension Strawberry Flavour

### Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to give it 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
- 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

### What this medicine is for

This medicine 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. It can be used for the fast, effective relief of mild to moderate pain such as teething pain, toothache, earache, sore throat, headaches and 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.

### Before you give this medicine

This medicine can be given to children from the age of 3 months. However, some children should not be given this medicine or you should seek the advice of their pharmacist or doctor first.

#### X Do not give:

- **If your child is under 3 months old**, or weighs less than 5 kg
- **If your child has a stomach ulcer, perforation or bleeding**, or has had one twice or more in the past
- **If your child has had perforation or a bleeding stomach** after taking a non-steroidal anti-inflammatory 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)
- **If your child is allergic** to ibuprofen or any other ingredients in this medicine, aspirin or other non-steroidal anti-inflammatory medicines (your child has ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- **If your child has severe heart, kidney or liver failure**
- **If your child is taking aspirin with a daily dose above 75 mg**, or other non-steroidal anti-inflammatory medicines (aspirin should not generally be given to children under 16, but doctors may occasionally prescribe it)

### Other important information

If you are taking this medicine 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 'Possible side effects').

**Risk of heart attack or stroke:** Anti-inflammatory/painkiller 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.

**Take special care with Ibuprofen 3 Months Plus Suspension.**

**Skin reactions:** Serious skin reactions have been reported in association with ibuprofen treatment. You should stop giving this medicine 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 'Possible Side Effects'.

**! Talk to your pharmacist or doctor:**

- If your child has asthma, a history of asthma or other allergic disease
- If your child has bowel problems, or Crohn's Disease
- If your child has other kidney, heart or liver problems (see above)
- If your child has connective tissue disorders such as SLE (Systemic Lupus Erythematosus)
- If your child has chickenpox
- If your child is on a low salt (sodium) diet (this medicine contains 11 mg of sodium per 5 ml spoonful)
- If your child is dehydrated – they may get kidney problems
- If your child has heart problems including heart failure, angina (chest pain), or has 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") – see '**Risk of heart attack or stroke**' under "Other important information"
- If your child has high blood pressure, diabetes, high cholesterol, has a family history of heart disease or stroke
- If your child has an infection - please see heading 'Infections' below

**If your child takes other medicines**

Before you give this medicine, make sure that you tell your doctor or pharmacist about ANY other medicines you might be giving to the child at the same time. Ibuprofen may affect or be affected by some other medicines. For example:

- Other painkillers (including NSAIDs)
- Aspirin 75 mg (to prevent heart attacks or strokes) – the protection may be reduced when you take ibuprofen
- Medicines to thin the blood (e.g. warfarin, ticlopidine)
- Water tablets (diuretics)
- Medicines to treat high blood pressure (e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan), medicines for heart problems
- Corticosteroids (for pain and swelling)
- Lithium (for bipolar disorder)
- Methotrexate (for cancer, psoriasis or rheumatism)
- Zidovudine (for HIV infection)
- Quinolone antibiotics (for infection)
- Medicines for depression (including selective serotonin re-uptake inhibitors)
- Ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)

Some other medicines may also affect or be affected by the treatment of Ibuprofen. You should therefore always seek advice of your doctor or pharmacist before your child uses this medicine with any other medicines, including herbal and homeopathic remedies.

## Other information

**Infections:** Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that Boots Ibuprofen 3 Months Plus 100mg/5ml Oral Suspension Strawberry Flavour 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 your child takes this medicine while they have an infection and their symptoms of the infection persist or worsen, consult a doctor without delay.

Information about some of the ingredients:

**Maltitol liquid** may have a mild laxative effect. Each 5 ml spoonful contains 2.1 g maltitol. This provides 5 kcal per 5 ml spoonful. If your child has been told by their doctor that they have an intolerance to some sugars, contact their doctor before taking this medicinal product.

**Sodium** this medicine contains 11 mg sodium (main component of cooking/table salt) in each 5 ml dosage. This is equivalent to 1.65% of the recommended maximum daily dietary intake of sodium for a child. A maximum dosage of 15 ml would provide 33 mg of sodium and so this should be taken into consideration by children on a controlled sodium diet.

### Information for adults intending to take this medicine

All the information in this leaflet applies to you as well.

**If you are elderly** you may be more likely to have some of the possible side effects listed later in the leaflet.

**If you have had a stroke, have heart problems, you smoke, have high blood pressure, high cholesterol or diabetes** talk to your pharmacist or doctor before you take this medicine (see "Risk of heart attack or stroke" above).

**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.

**Breastfeeding:** If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

**If you are a woman of childbearing age** taking this medicine, it may reduce your ability to become pregnant. This effect will be reversed on stopping the medicine.

Do not take this medicine if you have taken mifepristone (for termination of pregnancy) in the last 12 days.

### ✓ How to give this medicine

Check the cap seal is not broken before first use. If it is, do not give the medicine.

It is important to **shake the bottle** for at least 10 seconds before use.

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

Give this medicine to your child to swallow.

Age	How much	How often
3 months up to 6 months <b>weighing over 5 kg</b>	2.5 ml	3 times in 24 hours
6 months up to 1 year	2.5 ml	3 to 4 times in 24 hours
1 year up to 4 years	5 ml	3 times in 24 hours
4 years up to 7 years	7.5 ml	3 times in 24 hours
7 years up to 10 years	10 ml	3 times in 24 hours
10 years up to 12 years	15 ml	3 times in 24 hours
<b>Don't give more often</b> than every 4 hours		

**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).

**For infants aged 3 to 5 months,** if symptoms worsen or do not go away within 24 hours, talk to your doctor.

**For a child of 6 months of age and over,** if this medicinal product is required for more than 3 days, or if symptoms worsen talk to your doctor.

**For fever relief after vaccination at 3 months of age:** Give 2.5 ml. Give a second 2.5 ml after 6 hours, if you need to. **Don't give any more medicine after second 2.5 ml.** See a doctor if fever continues.

Do not give more than the amount recommended above.

Do not give to children under 3 months of age.

#### **Directions for using the syringe:**

1. **Shake the bottle** for at least 10 seconds before use.
2. Push the syringe firmly into the plug (hole) in the neck of the bottle.
3. 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 (2.5 ml or 5 ml) on the syringe.
4. Turn the bottle the right way up, and then gently twist the syringe to remove from the bottle plug.
5. 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.
6. If the table above advises you to give more than 5 ml 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 give more than you should:** If you have given more than you should, or if children have taken the medicine by accident always contact a doctor or nearest hospital to get an opinion on 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.

## **Possible side effects**

Most people will not have problems, but some may get some.

**! If your child gets any of these serious side effects, stop giving the medicine. See a doctor at once:**

- Your child is sick and it contains blood or dark particles that look like coffee grounds
- Pass blood in their stools or pass black tarry stools
- Tiredness or severe exhaustion, changes in the blood which may cause unusual bruising or unexplained bleeding and an increase in the number of infections that they get (e.g. sore throats, mouth ulcers, flu-like symptoms including fever)
- Stomach problems including pain, indigestion or heartburn
- Unexplained wheezing (asthma), worsening of existing asthma, difficulty in breathing, swelling of the face, tongue, neck or throat, fast heart rate, fainting, dizziness or collapse (severe allergic reactions)
- Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering and lesions of the skin)
- Frequency "Not known": 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 giving this medicine if your child develops these symptoms and seek medical attention immediately. See also "Before you give this medicine"
- Worsening of existing severe skin infections (you may notice a rash, blistering and discolouration of the skin, fever, drowsiness, diarrhoea and sickness), or worsening of other infections including chickenpox or shingles
- 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)
- Meningitis (e.g. stiff neck, fever, disorientation)
- High blood pressure, heart failure, (your child may be tired, have difficulty breathing or swollen legs)
- A small increased risk of heart attack or stroke if you take large amounts for a long time
- Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)
- Swellings or ulcers of the stomach
- Kidney problems, which may lead to kidney failure (your child may pass more or less urine, have blood in the urine or cloudy urine, or feel breathless, very tired or weak, have no appetite, or have swollen ankles)

**If your child gets any of the following side effects see your pharmacist or doctor:**

- Uncommon, feeling sick or rarely, being sick
- Uncommon, headache
- Rarely, diarrhoea, constipation and wind, and very rarely, worsening of colitis or Crohn's disease
- Frequency not known, swellings or ulcers of the mouth lining, fluid retention, which may cause swelling of the limbs. Skin becomes sensitive to light.

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 'Other important information'). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

### **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](http://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.

### **How to store this medicine**

Do not store above 25°C.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton.

### **What is in this medicine**

Each 5 ml of oral suspension contains Ibuprofen 100 mg, which is the active ingredient.

As well as the active ingredient, the suspension also contains purified water, maltitol liquid (E965), glycerol (E422), xanthan gum, sodium citrate, citric acid, sodium saccharin, sodium chloride, polysorbate 80, domiphen bromide, strawberry flavour.

The pack contains 30, 50, 100, 150 or 200ml of off white, strawberry-flavoured syrupy suspension. Not all pack sizes may be marketed.

### **Who makes this medicine**

Manufactured for the Marketing Authorisation holder The Boots Company PLC Nottingham NG2 3AA by BCM Ltd Nottingham NG2 3AA

Leaflet prepared December 2022.

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA

Artwork reference number: XBCT6