

Information for the user



3 Months Plus Ibuprofen 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.

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 taking this medicine immediately and immediately contact your doctor or medical emergency department if you notice any of these signs.

Take special care with 3 Months Plus Ibuprofen Oral Suspension.

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 possible side effects section.

! Talk to your pharmacist or doctor:

- If your child has asthma, a history of asthma or other allergic disease
- If your child suffers from chronic inflammatory bowel disease such as Crohn's Disease or ulcerative colitis
- 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 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. 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 you take this medicine while you have an infection and your 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 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 up to 75 mg a day (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)
- Antiplatelet drugs (dipyridamole, clopidogrel)

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

Other information

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. May have a mild laxative effect. Calorific value 2.3kcal/g maltitol.

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 of 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 talk to your doctor before using this medicine. 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).

If you are pregnant: 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 weighing over 5 kg	2.5 ml	3 times in 24 hours 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 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
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.		

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 6 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 for infants weighing more than 5kg: 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 or babies weighing less than 5kg.
For short term use only.
For patients with sensitive stomachs the medicine can be taken with or after food.

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 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 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.

! 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.**

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, skin rash (which may be severe with

blistering or peeling of the skin), itching or bruising, severe skin reactions including Stevens-Johnson syndrome, racing heart, fluid retention (swollen ankles or decreased levels of passing urine)

- stiff neck, headache, nausea, vomiting, fever and disorientation.
- face, tongue or throat swelling (these can be signs of serious allergic reactions)
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- 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).
- 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]
- 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 also "Before you give this medicine"

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)
- 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 the kidneys and affect them removing acids properly from the blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in the 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 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

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