



- This medicine brings down high temperature (also called fever) and relieves pain such as muscular pain, headache, earache, dental pain, backache and symptoms of cold and flu.
- The medicine is OK for most babies over 3 months, children and adults.
- The active ingredient in this medicine is ibuprofen which is a **non-steroidal anti-inflammatory (NSAID) painkiller**.
- **Follow the dosage instructions carefully.** Children of different ages need different amounts. These are shown in the table. See section 3 ►
- **Speak to your doctor if anything in this list applies:**
  - If a child suffers from any of the conditions mentioned in section 2. See section 2 ►
  - If a child is taking aspirin at doses of above 75 mg a day. See section 2 ►
  - If a child is taking any other medicines. See section 2 ►
  - If a child is not getting better, or needs more medicine than shown in the table. See section 2 ►
  - If a child gets a rash, breathing problems, diarrhoea or gets very tired. See section 3 ►
  - If the symptoms persist or worsen. See section 3 ►
- **Do not use this product and speak to your doctor if you are trying to get pregnant, suspect you are pregnant, are pregnant or are breast-feeding.** See section 2 ►

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet; you might need it again.

## 1 What the medicine is for

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory painkillers (NSAIDs).

The ibuprofen in CALPROFEN<sup>®</sup> is used as an analgesic for relief of mild to moderate muscular pain, symptomatic relief of headache, earache, dental pain, backache and relieves the symptoms of cold and flu. It can also be used in minor injuries such as sprains and strains. CALPROFEN<sup>®</sup> also brings down high temperature including post-immunisation fever.

## 2 Before giving the medicine to your child

This product is suitable for most people but a few people should not use it. If you are in any doubt you should contact your doctor or pharmacist.

### X Do not give your child this medicine...

- If s/he has ever had a **bad reaction** (e.g. asthma, runny nose, swelling of face, tongue and throat, rash) after taking ibuprofen, any of the other ingredients (see section 6), **aspirin** or **non-steroidal anti-inflammatory (NSAID) painkillers**.
- If s/he weighs less than 5 kg.
- If s/he is taking any other **anti-inflammatory painkillers (NSAIDs)** or **aspirin** with a daily dose above 75 mg.
- If s/he has (or has had two or more episodes of) a **stomach ulcer, perforation or bleeding**.
- If s/he has **severe kidney, heart or liver failure**.

If any of these apply, get advice from a doctor or pharmacist without using CALPROFEN<sup>®</sup>.

### A Talk to your doctor or pharmacist...

- If your child has or has previously had **high blood pressure, heart problems or a stroke** because there is a small increased risk of heart problems with ibuprofen.
- If your child has any conditions which may put them at risk of **heart problems** e.g. suffers from **diabetes, has high cholesterol**.
- If your child has **asthma or allergic diseases of the lungs**.
- If your child has or has previously had **liver, kidney, heart or bowel problems, or is dehydrated**.
- If your child suffers from **leukaemia (SLE)** or a similar disease.
- If your child suffers from a **chronic inflammatory bowel disease** such as Crohn's disease or ulcerative colitis.
- **If your child is taking any other medicines** including:
  - low-dose **aspirin** (up to 75 mg a day),
  - **diuretics** (drugs to help pass water e.g. bendroflumethazide),
  - **anticoagulants** (drugs that **thin the blood**, such as warfarin),
  - **antihypertensives** (drugs used to treat **high blood pressure**, such as verapamil or propranolol),
  - **lithium** (used to treat **mood disorders**),
  - **methotrexate** (used to treat **arthritis, some types of cancer and psoriasis**),
  - **zidovudine** (used to treat **HIV**),
  - **cardiac glycosides** (drugs used in the treatment of **heart failure and arrhythmias (abnormal heart rhythm)** e.g. Digoxin
  - **clozapine** (used to **suppress the body's immune system e.g. following a transplant**),
  - **mifepristone** (used for **termination of pregnancy**),
  - **quinolone antibiotics** (used to treat a wide range of **infections**, e.g. ciprofloxacin),
  - **SSRI antidepressants** (e.g. fluoxetine),
  - **antiplatelet drugs** (e.g. clopidogrel),
  - **lacritolus in transanal irrigation**,
  - **any other ibuprofen preparations or NSAID painkillers**, including those you can buy without a prescription.

If you are not sure about any of the medicines your child is taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply, **talk to a doctor or pharmacist**.

### A If your child experiences the following, stop giving this medicine immediately and contact your doctor

- Serious skin reactions have been reported in association with this medicine. 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.

### A If adults take this medicine:

The above warnings and information apply and in addition the following:

- Ibuprofen belongs to a group of medicines which may impair fertility in women. The effect is reversible on stopping the medicine. It is unlikely that ibuprofen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.
- You should only take this product on a doctor's advice during the first 6 months of pregnancy.
- Do NOT take ibuprofen if you are in the last 3 months of pregnancy due to potential harm to the unborn child.
- Speak to your doctor or pharmacist before using this product if you are elderly or are a smoker.

### Some of the ingredients can cause problems

- Sodium methylhydroxybenzoate (E210) and sodium propylhydroxybenzoate (E217) may cause allergic reactions which could possibly be delayed.
- This product contains maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Maltitol may have a mild laxative effect. Caloric value 2.3 kcal/g maltitol.
- This medicine contains 4.67 mg propylene glycol (E1520) in each 5 ml dose, which is equivalent to 0.93 mg/ml.
- This medicinal product contains small amounts of ethanol (alcohol), not more than 100 mg per 5 ml dose.

## 3 How to use this medicine

Check the information below to see how much medicine to use.

- Always **shake the bottle** thoroughly before use.
- Do not use more medicine than shown in the instructions below.
- Always use the syringe supplied with the pack.

### I How to use the syringe

- Shake the bottle for at least 10 seconds and remove the cap.
- There is a plug with a hole in the neck of the bottle. Insert the end of the syringe in to the hole and ensure it is secure.
- Hold the syringe in place and turn the bottle upside down and gently pull down the plunger to either 2.5 ml or 5 ml as appropriate (see tables for the correct dose).
- Turn the bottle the right way up.
- Remove the syringe by holding onto the bottle and twisting out gently.

turn over ►

- Place the syringe inside the child's mouth against the cheek and press the plunger slowly to gently release the medicine.
- After use, the plug should remain in the neck of the bottle. Wipe the plug and neck clean and rinse the cap before replacing.
- The syringe should be washed and dried after use. It should be cleaned by hand without removing the plunger.

### I Babies under 3 months

Do not give to babies under 3 months. Consult your doctor.

### I Children from 3 months to 12 years

#### For Pain and Fever Relief:

Age	Dose
3 months - 6 months	2.5 ml 3 times a day
= weighing over 5 kg	Do not use for more than 24 hours
6 months - 1 year	2.5 ml 3 times a day
1 year - 2 years	2.5 ml 3 or 4 times a day
3 years - 7 years	5 ml 3 or 4 times a day
8 years - 12 years	10 ml (5 ml + 5 ml) 3 or 4 times a day

■ Doses should usually be given every 6 - 8 hours. Leave at least 4 hours between doses.

■ Short term use only:

- Do not give to babies aged from 3 months to under 6 months for more than 24 hours.
- Do not give to children aged 6 months or over for more than 3 days.
- If symptoms persist or worsen consult your doctor.

#### For Post-Immunisation Fever:

Age	Dose
Babies and children 3 months and over	2.5 ml up to twice a day
= weighing over 5 kg	

If necessary, the second dose should be given 6 hours after the first one.

- Do not give more than 2 doses in 24 hours.
- Do not give to a child under 3 months unless recommended by your doctor.
- If the fever is not reduced you should consult your doctor.

### A Speak to your doctor

- If your baby needs more than the dose shown in the table, or if the fever doesn't go away, speak to your doctor as soon as possible.
- If you are not sure of your child's illness or if it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness or lethargy, speak to your doctor straight away. Do not give CALPROFEN<sup>®</sup> until you get medical advice.

### A If anyone has taken too much

If anyone has taken too much of this product, contact a doctor or your nearest Accident and Emergency Department (Casualty), taking this leaflet and pack with you.

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.

### A 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 take a double dose.

## 4 Possible side-effects

CALPROFEN<sup>®</sup> can have side-effects, like all medicines, although these don't affect everyone and are usually mild. The most common side-effect is irritation of the stomach which can cause problems (e.g. indigestion, heartburn) in some patients.

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

- blood in the faeces (stools/motions).
- black tarry stools.
- vomiting blood or dark particles that look like ground coffee
- unexplained wheezing, shortness of breath, skin rash (which may be severe and include blistering or peeling of the skin), itching or bruising, light-headedness or racing heart or fluid retention e.g. swollen ankles or decreased levels of urine passed.
- stiff neck, headache, nausea, vomiting, fever and disorientation.
- 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 cell).
- 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). See also section 2.

If your child experiences any of the following, stop giving this medicine and tell your doctor:

- unexplained stomach pain, indigestion, heartburn, feeling sick and/or vomiting.
- yellowing of the eyes and/or skin, which may be a sign of liver problems.
- severe sore throat with high fever.
- unexplained bruising or tiredness or getting more infections (such as colds) than usual.

### Other effects which may occur are listed below:

- Uncommon:**
- headache.
- Rare:**
- diarrhoea, wind or constipation. If any of these become troublesome or last more than a few days, tell your doctor.
- Very rare:**
- kidney problems may occur with ibuprofen.
  - stroke or heart problems may occur with ibuprofen, but this is very unlikely at the doses given to children.
  - worsening of colitis and Crohn's disease.

### Other effects reported include:

- high blood pressure.
- If your child experiences any side-effects not included in this leaflet or you are not sure about anything, **talk to your doctor or pharmacist**.

### 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](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.

## 5 Storing this medicine

Do not take your medicine after the expiry date shown on the bottle.

Do not store above 25°C.

Keep this medicine out of the sight and reach of children.

## 6 Further Information

### What's in this medicine?

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

**Other ingredients are:** Glycerol (E422), xanthan gum, maltitol (E965), polyethylene glycol, sodium citrate (E331), citric acid monohydrate, sodium methylhydroxybenzoate (E210), sodium propylhydroxybenzoate (E217), purified water. The flavouring is strawberry (containing propylene glycol (E1520) and ethanol).

### What the medicine looks like

CALPROFEN<sup>®</sup> is a whitish liquid available in 200 ml bottles. It contains 100 mg of the active ingredient ibuprofen in every 5 ml of medicine.

**Product Licence holder:** McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

**The manufacturer is:** McNeil Iberica S.L.U., 28005 Madrid, Spain.

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**For further information please contact:**

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