Calprofen®

Ibuprofen
Suspension

- 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 3* ►
  - 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 breastfeeding.** *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® 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® also brings down a 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.**
- **Immediately before or after heart surgery.**

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

! Talk to your doctor or pharmacist…

- If your child has an **infection** - please see heading "**Infections**" below.
- If your child has or has previously had **high blood pressure, heart or artery problems or a stroke** because there is a small increased risk of a heart attack or stroke 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,** or if there is a **family history of heart disease or stroke.**
- 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 **lupus (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 you pass water** e.g. bendroflumethiazide).
  - *anticoagulants* (drugs that **thin the blood**, such as warfarin and ticlopidine).
  - *antihypertensives* (drugs used to treat **high blood pressure**, such as verapamil, ACE-inhibitors such as captopril, beta-blockers such as propranolol or atenolol, angiotensin-II receptor antagonists such as losartan).
  - *lithium* (used to treat **mood disorders**).
  - *methotrexate* (used to treat **arthritis, some types of cancer and psoriasis**).
  - *zidovudine* (used to treat **HIV**).
  - *corticosteroids* (a type of **anti-inflammatory** drugs, e.g. hydrocortisone).
  - *cardiac glycosides* (drugs used in the treatment of **heart failure and arrhythmias (abnormal heart rhythm)** e.g. digoxin).
  - *ciclosporin* (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).
  - *tacrolimus* (a **transplant** drug).
  - *any other ibuprofen preparations or NAID painkillers*, including those you can buy without a prescription.

Infections

This medicine 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 your child takes this medicine while they have an infection and their symptoms of the infection persist or worsen, consult a doctor without delay.

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.**

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

- 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 CALPROFEN® and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- 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. Immediately stop CALPROFEN® and contact your doctor or Emergency Department (Casualty) if you notice any of these signs.

! 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.
- 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.
- Speak to your doctor or pharmacist before using this product if you are elderly or are a smoker.
- You should be careful when taking ibuprofen with excessive alcohol as it may increase the risk of bleeding from your intestine.

Some of the ingredients can cause problems

- Sodium methylhydroxybenzoate (E219) 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. Calorific 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 medicine contains 0.0005 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

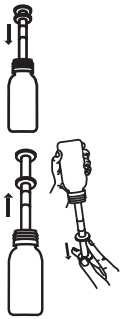
3 How to use this medicine

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.
- 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).
- Always use the syringe supplied with the pack.

turn over ►

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.
- 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.

Babies under 3 months

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

Children from 3 months to 12 years

For Pain and Fever Relief:

Age	Dose
3 months - 6 months ■ weighing over 5 kg	**2.5 ml** 3 times a day. 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 ■ weighing over 5 kg	**2.5 ml** up to twice a day

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.

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 it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness or lethargy, speak to your doctor straight away. Do not give CALPROFEN® until you get medical advice.

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, and shaky eye movement. At high doses, lack of energy, drowsiness, chest pain, palpitations, confusion, loss of consciousness, convulsions, weakness and dizziness, blood in urine, muscle pain, cold body feeling, and breathing problems (mainly in children) have been reported.

Taking this medicine for longer than the recommended time or at higher than recommended doses, anyone is at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

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

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 (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.
- a severe allergic reaction which may cause swelling of the face, tongue or throat, wheezing, shortness of breath, skin reddening or rash (which may be severe and include blistering or peeling of the skin), itching, light-headedness or fainting due to a fall in blood pressure, racing heart or fluid retention e.g. swollen ankles or less urine passed than normal.
- 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).
- 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 localized on the skin folds, trunk, and upper extremities accompanied by fever usually at the initiation of treatment (acute generalised exanthematous pustulosis). See also section 2.
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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.
- liver, kidney problems or difficulty urinating.

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

Other effects which may occur are listed below:

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

Rare (may affect up to 1 in 1,000 people):
- diarrhoea, wind or constipation. If any of these become troublesome or last more than a few days, tell your doctor.
- bleeding from an ulcer in the intestine.

Very rare (may affect up to 1 in 10,000 people):
- 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 which may occur but it is unknown how often:
- high blood pressure.
- skin becomes sensitive to light.

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 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.
Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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), polysorbate 80, saccharin sodium (E954), citric acid monohydrate, sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), purified water. The flavouring is strawberry (containing propylene glycol (E1520) and ethanol).

What the medicine looks like

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

The Marketing Authorisation holder is McNeil Products Limited, 1 Station Hill Square, Station Hill, Reading, RG1 1LN, UK

The manufacturer is McNeil Iberica S.L.U., 28805 Madrid, Spain.

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For further information please contact:
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