

Package leaflet: Information for the user

**Brufen® Paediatric 100mg/5ml Oral suspension**  
ibuprofen

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you**

- Keep this leaflet. You may need to read it again.
- If you have further questions ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Brufen is and what it is used for
2. What you need to know before you take Brufen
3. How to take Brufen
4. Possible side effects
5. How to store Brufen
6. Contents of the pack and other information

The full name of your medicine is **Brufen Paediatric oral suspension**. In this leaflet, the shorter name Brufen is used.

## **1. What is Brufen and what it is used for**

Brufen belongs to a group of medicines called anti-inflammatory pain killers.

The active ingredient in Brufen is ibuprofen and each 5ml spoonful contains 100mg of ibuprofen.

It can be used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine (ankylosing spondylitis), swollen joints, frozen shoulder, bursitis, tendonitis, tenosynovitis, lower back pain, sprains and strains.

Brufen can also be used to lower temperature and to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine and to reduce fever in children.

## **2. What you need to know before you take Brufen**

### **Do not take Brufen**

- if you are allergic to ibuprofen or any of the ingredients of this medicine (listed in section 6)
- if you previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)

- if you currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past
- if you suffer from severe heart failure, liver failure or kidney failure
- if you have a condition which increases your tendency to bleeding
- if you are sensitive (allergic) or previously had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers
- if you are in the third trimester (last 3 months) of pregnancy
- if you have fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency

Do not take Brufen if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse.

### **Warnings and precautions**

#### **Talk to your doctor, pharmacist or nurse before taking Brufen**

- if you have, or previously suffered from bronchial asthma, chronic rhinitis or allergic diseases
- if you suffer from liver, kidney or heart disease
- if you suffer from high blood pressure (hypertension)
- if you are elderly – elderly people are more prone to side effects to NSAIDs, particularly stomach bleeding and perforation which can be fatal
- if you have been told by your doctor that you have an intolerance to some sugars
- if you have, or you previously had a stomach ulcer, stomach bleeding or other gastric complaint
- if you are dehydrated- there is a risk of renal impairment in dehydrated children, adolescents and the elderly
- if you have a condition which increases your tendency to bleeding or have bleeding in the skull – please see above
- if you have lupus or a connective tissue disease (autoimmune diseases affecting connective tissue)
- if you have an infection – please see heading “Infections” below
- During chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

#### **Heart attack and stroke**

Anti-inflammatory/pain-killer medicines like Brufen 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.

You should discuss your treatment with your doctor or pharmacist before taking Brufen if you:

- have heart problems including heart failure, angina (chest pain) or you have had a heart attack, bypass surgery or 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”).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker

### **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 Brufen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

### **Allergic reactions**

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

### **Infections**

Brufen may hide signs of infections such as fever and pain. It is therefore possible that Brufen 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.

### **Children and adolescents**

There is a risk of renal impairment in dehydrated children and adolescents.

### **Other medicines and Brufen**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Brufen may affect or be affected by some medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, heparin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol or angiotensin-II receptor antagonists such as losartan)

Some other medicines may affect or be affected by treatment with Brufen. You should therefore always seek the advice of your doctor or pharmacist before you use Brufen with other medicines.

In particular you should tell your doctor or pharmacist if you are taking any of the following medicines in addition to those mentioned above:

- any medicines used to treat high blood pressure (see above)
- any medicines to treat heart conditions (e.g. diuretics such as bendroflumethiazide or furosemide or cardiac glycosides such as digoxin)
- any anti-coagulants or anti-platelet medicines (see above)
- lithium or selective serotonin reuptake inhibitors (SSRIs) (used to treat depression)
- a medicine called zidovudine (an anti-viral drug)
- a medicine called methotrexate (used to treat some forms of cancer)
- medicines called cyclosporin or tacrolimus (immunosuppressants used following organ transplant or in autoimmune conditions such as psoriasis, eczema)

- any other NSAIDs or anti-inflammatory pain killers, including aspirin and the group of drugs known as COX-2 inhibitors such as celecoxib and lumiracoxib
- any corticosteroids (e.g. hydrocortisone, betamethasone, prednisolone, used to treat inflammatory conditions)
- a certain type of antibiotic, known as quinolone antibiotics (e.g. ciprofloxacin and levofloxacin)
- a certain type of antibiotic known as aminoglycosides
- mifepristone (used for the medical termination of pregnancy)
- any oral medicines used to treat diabetes (e.g. metformin, or any sulphonylurea medicines)
- a herbal remedy called ginkgo biloba (there is a chance that you may bleed more easily if you are taking ibuprofen and ginkgo biloba at the same time).
- cholestyramine (used to treat high cholesterol levels)
- voriconazole or fluconazole (anti-fungal drugs)

### **Brufen with alcohol**

If you drink alcohol while taking this medicine you may be more likely to get side effects.

### **Pregnancy, breast-feeding and fertility:**

Do not take ibuprofen 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 ibuprofen 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 more than a few days from 20 weeks of pregnancy onward, ibuprofen 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 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.

Brufen is not recommended while breastfeeding.

Brufen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

### **Driving and using machines**

Medicines such as Brufen may cause dizziness, drowsiness, tiredness and problems with vision. If affected, you should not drive or operate machines. Also you should not do anything else where you need to be alert. This particularly applies in combination with alcohol.

### **What else do you need to know about Brufen**

Do not take Brufen Paediatric Oral Suspension if you are allergic to aspirin. If you develop an unexpected skin rash, sore eyes, sore mouth or difficulty breathing whilst taking the medicine, stop taking it and contact your doctor for advice.

**Brufen contains sucrose, sorbitol, colouring agent Sunset Yellow (E110), methyl parahydroxybenzoate, propyl parahydroxybenzoate and sodium benzoate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Brufen contains 3.3 g sucrose per 5 ml dose. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth.

This medicine contains 500 mg sorbitol in each 5 ml oral solution. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you 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 you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Brufen contains colouring agent Sunset Yellow (E110) which may cause allergic reactions.

Brufen contains the preservatives methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

This medicine contains 12.5 mg sodium benzoate in each 5 ml oral solution. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine contains less than 1 mmol sodium (23 mg) per 5ml dose, that is to say essentially 'sodium-free'.

### 3. How to take Brufen

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Brufen can be taken with a little water, preferably with or after food.

Remember to shake the bottle before use.

It is recommended that patients with sensitive stomachs take ibuprofen with food.

#### The recommended dose is

*Adults and adolescents:* The usual dose is four to six 5 ml spoonfuls taken three times each day. Your doctor may choose to increase or decrease this dose depending on your symptoms, but no more than 120 ml of oral suspension (2400 mg) should be taken each day.

*Children:* The usual dose in children is 20 mg to 30 mg per kg of bodyweight each day, in divided doses.

This can be given as follows:

Age/weight	Frequency	Single dose
3-6 months (~5-7kg)	Up to 3 times a day	2.5ml (50mg)
6-12 months (~7-10kg)	3 times a day	2.5ml (50mg)
1 to 2 years (~10-14.5kg)	3 to 4 times a day	2.5ml (50mg)
3 to 7 years (~14.5-25kg)	3 to 4 times a day	5ml (100mg)
8 to 12 years	3 to 4 times a day	10ml

(~25-40kg)		(200mg)
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The doctor may choose to increase this dose in children with severe arthritis to 40mg/kg of bodyweight daily, if needed. In children weighing less than 30 kg, no more than 500 mg of Brufen should be given each day.

*Elderly:* – Refer to adult dosing. If you have liver or kidney problems however, your dose may need to be modified in which case you should contact your doctor for advice.

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).

A transient sensation of burning in the mouth or throat may occur with ibuprofen suspension.

Avoid prolonged use of any painkillers as these may result in headaches that should not be treated with increased doses of Brufen. Tell your doctor if this occurs.

#### **If you take more Brufen than you should**

If you take more Brufen than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), headaches, 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, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported.

#### **If you forget to take Brufen**

- take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose.
- do not take a double dose to make up for a forgotten dose.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. You can minimise the risk of side effects by taking the least amount of medicine for the shortest amount of time necessary to control your symptoms.

#### **Serious side effects**

**Stop taking Brufen and seek medical attention immediately if you notice any of the following symptoms:**

#### ***Common (may affect up to 1 in 10 people):***

- signs of bleeding from the stomach or gut such as passing blood in your faeces (stools/motions), passing black tarry stools or vomiting any blood or dark particles that look like coffee grounds

**Uncommon (may affect up to 1 in 100 people):**

- swelling of the face, tongue or throat (larynx) which can cause great difficulty in swallowing and breathing (angioedema)

**Rare (may affect up to 1 in 1,000 people):**

- rapid heartbeat, severe fall in blood pressure or life threatening shock

**Very rare (may affect up to 1 in 10,000 people):**

- 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).
- severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle; this may occur in exceptional cases during chicken pox

**Not known (we do not know how often these happen):**

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome)
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever (acute generalised exanthematous pustulosis).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Stop taking this medicine and seek medical attention immediately if you notice any of the side effects above.

**Stop taking this medicine and tell your doctor if you notice any of the following:**

**Common (may affect up to 1 in 10 people):**

- indigestion or heartburn
- abdominal (stomach) pains or other abnormal stomach symptoms

Stop taking this medicine and tell your doctor if you notice any of the side effects above.

**Other side effects**

**Common (may affect up to 1 in 10 people):**

- rash
- feeling dizzy or tired
- loss of appetite, diarrhoea, feeling sick, being sick, wind, constipation
- headache - if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

**Uncommon (may affect up to 1 in 100 people):**

- feeling drowsy
- feeling anxious
- feeling a tingling sensation or 'pins and needles'
- difficulty sleeping

- hives, itching
- skin becomes sensitive to light
- visual disturbances, hearing problems
- ringing in ears (tinnitus)
- sensation of feeling dizzy or spinning (vertigo)
- hepatitis, yellowing of your skin or eyes, reduced liver function
- reduced kidney function, inflammation of the kidneys, kidney failure
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- small bruises on your skin or inside your mouth, nose or ears
- difficulty breathing, wheezing or coughing, asthma or worsening of asthma
- hypersensitivity reactions such as unexplained wheezing, shortness of breath, skin rash, itching or bruising

**Rare (may affect up to 1 in 1,000 people):**

- feeling depressed or confused
- fluid retention (oedema)
- a brain infection called 'non-bacterial meningitis'
- loss of vision
- changes in blood count - the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, feeling very tired, bleeding from the nose and the skin
- reduction in blood cells (anaemia)

**Very rare (may affect up to 1 in 10,000 people):**

- heart failure, heart attack, high blood pressure
- liver failure
- inflammation of the pancreas
- skin problems (which can also affect inside your mouth, nose or ears) such as 'Stevens-Johnson syndrome', 'toxic epidermal necrolysis' or 'erythema multiforme'.

**Not known (we do not know how often these happen):**

- prolonged bleeding time
- worsening of ulcers in the large intestine (colitis) or Crohn's Disease (bowel disease)
- A distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching

**The following side effects have also been reported with other NSAIDs:**

- high blood pressure or heart failure
- worsening of ulcers in the large intestine and Crohn's disease (bowel disease)
- a small increased risk of heart attack or stroke.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

**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 HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Brufen**

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

Do not use this medicine after the expiry date which is stated on the carton and bottle after 'EXP:'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Once opened, the contents of the bottle should be used within 12 months.

If your doctor decides to stop your treatment, return any leftover medicine to your pharmacist. Only keep the medicine if your doctor tells you to.

Do not throw away any 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. Contents of the pack and other information**

### **What Brufen contains**

- the active substance in Brufen is ibuprofen. Each 5 ml of oral suspension contains 100 mg ibuprofen.
- The other ingredients are: Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Sucrose, Citric Acid Monohydrate, Sodium Benzoate (E211), Agar BPC '54 Pdr, Glycerol, Sorbitol Solution Non-Crystallising (E420), Polysorbate 80, Sunset Yellow FC Edicol (E110), Orange Flavour D717 BBA, Purified Water.  
See Section 2 (Brufen Paediatric Oral suspension contains the following ingredients) for further details.

### **What Brufen looks like and contents of the pack**

- The product is supplied in bottles containing 200ml of oral suspension.
- Brufen Paediatric oral suspension is an orange coloured and flavoured syrup-like suspension.

Each pack contains 1 x 200ml bottle.

### **Marketing Authorisation Holder and Manufacture:**

*Marketing Authorisation Holder*

Viartis Healthcare Limited,  
Damastown Industrial Park,  
Mulhuddart, Dublin 15,  
DUBLIN, Ireland.

*Manufacturer:*

AbbVie S.r.l.

S.R. 148 Pontina km 52 snc

04011 Campoverde di Aprilia (LT)

Italy.

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