

## **Package leaflet: Information for the user**

### **Brufen 20 mg/ml 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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on 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 or pharmacist. 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

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

Brufen oral suspension contains the active substance ibuprofen and belongs to a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Brufen relieves pain, reduces fever and has an anti-inflammatory effect.

Brufen oral suspension is used for pain of mild to moderate intensity, rheumatic conditions (rheumatoid arthritis, osteoarthritis) and menstrual pain, by adults and adolescents over 12 years old (40 kg and above).

For children 6 months -12 years, Brufen oral suspension is used during acute painful conditions and fever associated with common cold.

The effect of Brufen is achieved usually within 30 minutes.

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

##### **Do not take Brufen:**

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if you have stomach ulcer or duodenal ulcer or have had recurrent ulcer or bleeding in the stomach or intestine
- if you have severe liver or kidney disease
- if you have severe heart failure
- if you have an increased tendency to bleed
- if you previously have had bleeding or perforation in your stomach or intestine when treated with Brufen or a similar product (other NSAIDs).
- if you are in the last three months of pregnancy

- if you have experienced allergic reactions (e.g. breathing difficulties, nasal obstruction, rash) to acetylsalicylic acid or other anti-inflammatory drugs (NSAIDs).

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Brufen.

- if you have asthma, chronic rhinitis (chronic stuffy and runny nose) or allergic diseases since Brufen can cause difficulty breathing, hives or a serious allergic reaction when you have any of these conditions.
- if you have certain disorders of the immune system (mixed connective tissue disorders and systemic lupus erythematosus (SLE), conditions of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs) as there may be an increased risk of aseptic meningitis
- if you have impaired kidney or liver function
- if you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs of feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”).
- if you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- if you have inflammatory bowel diseases, previous stomach ulcer or other increased tendency to bleed.
- if you are dehydrated, as there is a risk of renal impairment, especially in dehydrated adolescents and the elderly.
- if you have an infection - please see heading “Infections” below.

Talk to your doctor or pharmacist before taking Brufen if any of the above applies to you.

Do not take Brufen if you are planning a pregnancy. Consult your doctor first. See also section “Pregnancy, breast-feeding and fertility”.

This product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine. See also section “Pregnancy, breast-feeding and fertility”.

### Lowest effective dose

Always aim for the lowest possible dose and shortest possible treatment time to reduce the risk of side effects. It is generally the case that higher than recommended doses can entail risks. This also means that the combination of several NSAID products at the same administration time should be avoided.

If you use painkillers for a long time, this can cause headaches, which should not be treated with more painkillers. If you think this applies to you, talk to your doctor or pharmacist

### Heart attack and stroke

Anti-inflammatory/pain-killer 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 immediately Brufen and contact immediately your doctor or medical emergencies if you notice any of these signs.

#### Gastrointestinal bleeding, ulceration or perforation

Patients who have previously had gastrointestinal tract problems, especially elderly patients, should contact a doctor in the event of abdominal symptoms (especially gastrointestinal bleeding), particularly at the start of treatment.

Treatment must be stopped and a doctor consulted when gastrointestinal bleeding or ulceration occurs during treatment with Brufen.

#### 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.

#### 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.

During chicken pox it is advisable to avoid use of this medicine.

#### Elderly

Elderly patients should be aware of their increased risk of adverse events, especially bleeding and perforation in the digestive tract, which may be fatal.

#### **Children and adolescents**

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

#### **Other medicines and Brufen**

Do not use different types of pain-relieving medicines at the same time unless directed by a doctor.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Brufen may affect or be affected by treatment with certain medicines, including those to treat/prevent:

- tumours and immune system disorders (methotrexate)
- manic depressive illness (lithium)
- irregular heart beat (digoxin)
- pain (acetylsalicylic acid)
- thromboembolic disorders (medicines that are anti-coagulants, i.e. thin blood/prevent clotting, e.g., aspirin/acetylsalicylic acid, dicumarol, warfarin, ticlopidine)
- depression (medicines called SSRIs - selective serotonin reuptake inhibitors)

- high blood pressure (medicines that reduce high blood pressure, e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan, diuretics)
- rejection in patients receiving organ transplants (medicines that suppress your immune system, such as ciclosporine or tacrolimus)
- inflammation (corticosteroids)
- bacterial infections (some antibiotics including aminoglycosides)
- fungal infections (e.g. voriconazole or fluconazole)
- diabetes mellitus (sulphonylureas)
- high cholesterol (cholestyramine)
- human immunodeficiency virus (HIV) infection (zidovudine)

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

### **Brufen with food, drink and alcohol**

Brufen can be used together with food and drinks. Brufen can be given on an empty stomach for faster relief. If Brufen is taken together with alcohol, side effects may be increased.

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

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### *Pregnancy*

Do not take Brufen 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 Brufen 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, Brufen 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.

#### *Breast-feeding*

Ibuprofen passes into breast milk but is not likely to have an effect on the breastfeeding child when used for short-term treatment. However, consult a doctor if using Brufen more than occasionally while breastfeeding is required.

#### *Fertility*

The use of ibuprofen may affect fertility. The use of ibuprofen is not recommended while attempting to conceive or during investigation of infertility.

### **Driving and using machines**

Brufen may impair reactions in some people, for example due to side effects such as visual disturbances, dizziness or drowsiness. This should be taken into consideration on occasions when high alertness is required, e.g. driving, and applies to a greater extent in combination with alcohol.

**Brufen contains sucrose, sorbitol, sunset yellow, sodium, sodium benzoate, methyl parahydroxybenzoate and propyl parahydroxybenzoate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Brufen oral suspension contains 3 g sucrose per 5 mL dose. This should be taken into account in patients with diabetes mellitus. May be harmful to teeth.

This medicine contains 500 mg sorbitol in each 5 ml oral suspension. 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 sunset yellow which may cause allergic reactions.

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

This medicine contains 12,5 mg sodium benzoate in each 5 ml oral suspension. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). Brufen oral suspension should not be given to children under the age of 6 months or children who weigh less than 7 kg.

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

### 3. How to take Brufen

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

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).

#### Adults and adolescents over 12 years old (40 kg and above)

*Rheumatic conditions:* The recommended dose is 20–35 ml (400–700 mg) 3 times daily. Allow 4-6 hours between doses. For faster relief of stiffness in the morning, the first dose can be given on an empty stomach. *Maximum daily dose:* 2400 mg.

*Menstrual pain:* The recommended dose is 20 ml (400 mg) 1-3 times daily, as required. Allow 4-6 hours between doses. Start treatment at the first signs of menstrual pain.

*Pain of mild to moderate intensity:* The recommended dose is 10–20 ml (200–400 mg) as a single dose or 3-4 times daily. Allow 4-6 hours between doses.

#### Use in children

*Acute pain and fever associated with cold, children 6 months - 12 years:* The recommended dose is 5–7.5 mg ibuprofen/kg body weight as a single dose or 20–30 mg/kg body weight per day according to the table below.

#### **Body weight should be used when calculating the dose (the ages given are approximate).**

<i>Weight</i>	<i>Age</i>	<i>Dose</i>
7–10 kg	6–12 months	2.5 ml 3 times daily
10–14.5 kg	1–2 years	2.5 ml 3–4 times daily
14.5–25 kg	3–7 years	5 ml 3–4 times daily
25–40 kg	8–12 years	10 ml 3–4 times daily

The dose should be given every 6 hours, up to four times daily. Brufen oral suspension should not be given to children under the age of 6 months or children who weigh less than 7 kg.

If you have severe liver and kidney disease or are elderly your doctor will tell you the correct dose to take which will be the lowest dose possible.

For a faster onset of action, Brufen may be taken on an empty stomach. However, if you have a sensitive stomach, take ibuprofen with food.

To help prevent a passing feeling of a burning sensation in the throat or mouth, ensure the bottle is thoroughly shaken before use.

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

If you have taken 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 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 take Brufen**

Do not use a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

***Stop taking Brufen and contact a doctor immediately if you develop any of the following:***

- Angioedema (an uncommon side effect) with symptoms such as:
  - swelling of the face, tongue or throat,
  - difficulties swallowing,
  - hives and difficulties breathing.
  
- An infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems. Brufen may cause a reduction in the number of white blood cells (agranulocytosis) with decreased resistance to infection (an uncommon side effect). It is important to inform your doctor about your medicine.
  
- Serious skin and mucous membrane changes such as epidermal necrolysis and/or erythema multiforme have been reported (a very rare side effect). In addition, 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). **Stop taking Brufen and contact a doctor** if you develop a rash or mucous membrane lesions. The severe rashes may include blisters on the skin, especially on the legs, arms, hands and feet which can also involve the face and lips. This can get even more severe, where the blisters get larger and spread out and parts of the skin may slough off (toxic epidermal necrolysis). There may also be severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle.

- 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). Frequency not known (frequency cannot be estimated from the available data). See also section 2.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome. Frequency not known (frequency cannot be estimated from the available data).

***Other side effects that may occur:***

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

- Headache, lightheadedness
- Gastrointestinal side effects (indigestion, diarrhoea, nausea, vomiting, abdominal pain, flatulence, constipation, black stools, bleeding in stomach and intestine, vomiting blood)
- Tiredness
- Rash

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

- Rhinitis
- Hypersensitivity
- Insomnia, anxiety
- Visual disturbances, hearing impairment
- Bronchial spasm, asthma
- Mouth ulceration
- Stomach ulcer, intestinal ulcer, ruptured stomach ulcer, inflammation of mucous membrane of stomach
- Hepatitis, jaundice, abnormal liver function
- Itching, small bruises in skin and mucous membranes
- Photosensitivity
- Impaired kidney function
- Changes in blood count
- Anaemia (a reduction in red blood cells or hemoglobin, which can make the skin pale and may lead to weakness)
- Drowsiness
- Tingling sensation
- Hearing loss

*Rare (may affect up to 1 in 1000 people):*

- Non-bacterial meningitis
- Allergic reaction
- Depression, confusion
- Impaired vision, tinnitus (ringing in ears), dizziness
- Liver damage and fluid retention in body

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

- Inflammation of the pancreas, liver failure

*Not known (frequency cannot be estimated from the available data):*

- Worsening of ulcers in the large intestine (colitis) and Crohn's Disease (bowel disease)
- Heart failure, heart attack, high blood pressure

Please note that Brufen can prolong bleeding time.

Exceptionally, serious infections of the skin in case of chicken pox. When an NSAID is used, an infection-related inflammation of the skin could develop or become more severe (e.g. a condition such as necrotising fasciitis may develop characterized by intense pain, high fever, swollen and hot skin, blistering, necrosis). If signs of an infection of the skin occur or get worse during use of Ibuprofen you are recommended to see your doctor immediately.

Medicines like Brufen may entail a slightly increased risk of heart attack or stroke.

A passing feeling of a burning sensation in the throat or mouth has also been reported with Brufen oral suspension.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V**. 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 package and bottle, after EXP. The expiry date refers to the last day of that month.

Opened bottle should be used within 12 months.

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 is ibuprofen. The suspension contains 20 mg/ml ibuprofen.
- The other ingredients are preservatives (methyl parahydroxybenzoate E218, propyl parahydroxybenzoate E216, sodium benzoate E211), sucrose, citric acid monohydrate, glycerol, sorbitol liquid (non-crystallising) E420, polysorbate 80, flavouring (orange), colorant (sunset yellow E110), agar, purified water.

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

Yellow oral suspension with orange flavour.  
100 ml and 200 ml (plastic bottle). A 5 ml dosing syringe / **a 2.5 ml/5 ml double dosing spoon** is included.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer:**

*Marketing Authorisation Holder:*

<To be completed nationally>

*Manufacturer:*

AbbVie S.r.l, Campoverde, Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

<b>Country</b>	<b>Product Name</b>
<b>Romania</b>	Brufen 20 mg/ml suspensie orală
<b>Slovenia</b>	Brufen 20 mg/ml peroralna suspenzija
<b>Sweden</b>	Brufen 20 mg/ml oral suspension

**This leaflet was last revised in**

20 February 2024