

BRUFEN® SYRUP 100mg/5ml
(ibuprofen)

Your medicine is known as Brufen Syrup 100mg/5ml but will be referred to as Brufen Syrup throughout the following leaflet.

IMPORTANT INFORMATION

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet as you may need to read it again
- This leaflet provides a summary of the information currently available about Brufen Syrup
- For further information or advice ask your doctor or pharmacist
- This medicine is for you only and should never be given to anyone else, even if they appear to have the same symptoms as you
- Tell your doctor or pharmacist if you experience any side effects

Leaflet Contents

1. What is Brufen Syrup & what is it used for?
2. What should you know before taking Brufen Syrup?
3. How should you take Brufen Syrup?
4. Possible side effects of Brufen Syrup.
5. How should you store Brufen Syrup?
6. Further information about Brufen Syrup.

1. WHAT IS BRUFEN SYRUP & WHAT IS IT USED FOR?

Brufen Syrup belongs to a group of medicines called anti-inflammatory pain killers. 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, tendinitis, tenosynovitis, lower back pain, sprains and strains.

Brufen Syrup can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine. It can also be used for the short term treatment of fever in children over the age of 1 year.

The active ingredient in Brufen Syrup is ibuprofen. Each 5ml spoonful of Brufen Syrup contains 100mg ibuprofen.

2. WHAT SHOULD YOU KNOW BEFORE TAKING BRUFEN SYRUP?

If the answer to any of the following questions is 'YES' please tell your doctor or pharmacist BEFORE taking any Brufen Syrup:

- Are you pregnant or planning to become pregnant, or are you breast-feeding? Brufen Syrup 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.
- Are you sensitive (allergic) to any of the ingredients in the syrup? These are listed in Section 6. Some people may be sensitive to the E110, methyl hydroxybenzoate, propyl hydroxybenzoate or sodium benzoate and if you develop an unexpected rash, sore eyes, sore mouth or difficulty breathing whilst taking the medicine stop taking it and contact your doctor for advice.
- Do you have, or have you previously had, a stomach ulcer or other gastric complaint? Do not take Brufen Syrup 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.
- Do you have a condition which increases your tendency to bleeding?
- Do you suffer from asthma or have you ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers?
- Do you suffer from swelling and irritation inside the nose?
- Do you suffer from liver or kidney disease?
- Do you suffer from heart disease?

Medicines such as Brufen Syrup may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. You should discuss your treatment with your doctor or pharmacist before taking Brufen Syrup 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).
- have any kind of stroke or think that you might be at risk of these conditions (e.g. if you have a family history of heart disease or stroke, high blood pressure, diabetes, high cholesterol or are a smoker).
- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- Do you have chicken pox or shingles?
- Have you been told by your doctor that you have an intolerance to some sugars? Due to the content of sorbitol (70 mg per ml or 2.8 g per dose) and sucrose (660 mg per ml or 26.4g per dose) it is not recommended for those with hereditary fructose intolerance, glucose malabsorption syndrome or sucrose isomaltase deficiency.
- Is your child dehydrated? As there is a risk of kidney damage in dehydrated children and adolescents.

Can you take Brufen with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin- II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen 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:

- diuretics (water tablets)
- cardiac glycosides, such as digoxin, used to treat heart conditions
- lithium
- zidovudine (an anti-viral drug)
- steroids (used in the treatment of inflammatory conditions)
- methotrexate (used to treat certain cancers and rheumatoid arthritis)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- mifepristone
- any other ibuprofen, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including aspirin
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Other information about Brufen Syrup:

The syrup contains small amounts of glycerin (glycerol). In high doses, glycerin may sometimes cause headache, stomach upset and diarrhoea. As such, you should not take more than the stated dose unless your doctor advises you to. The syrup contains sucrose and therefore may be harmful to your teeth.

Pregnancy and breast-feeding: The use of Brufen Syrup whilst pregnant or breast feeding should be avoided. Brufen Syrup should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and Using Machines: Brufen Syrup may make you feel dizzy or drowsy. If it affects you in this way do not drive, operate machinery or do anything that requires you to be alert.

3. HOW SHOULD YOU TAKE BRUFEN SYRUP?

ALWAYS take Brufen Syrup exactly as your doctor has told you. If you are not sure refer to the label on the carton or check with your doctor or pharmacist. Ensure the bottle is thoroughly shaken before use. Take with or after food.

DOSAGE:

Adults and children over 12 years -The usual dosage is 4 to 6 spoonfuls (5 ml) taken three times a day. Your doctor may choose to increase or decrease this depending on what you are being treated for; but no more than 24 spoonfuls (120 ml/2400 mg) should be taken in one day.

Children - Brufen Syrup should **NOT** be taken by children weighing less than 7 kg. When used to treat fever, the syrup should not be used long term or given to children under the age of 1 year.

The usual dose in children is 20 mg per kg of bodyweight each day, in divided doses. This can be given as follows:

1-2 years: One 2.5 ml (50 mg) dose three/four times a day

3-7 years: One 5 ml (100 mg) dose three/four times a day

8-12 years: Two 5 ml (200 mg) doses three/four times a day

The doctor may choose to increase this dose in children with juvenile rheumatoid arthritis. This dose should not exceed 40mg/ kg bodyweight daily in divided doses.

You should avoid excessive use of painkillers. If you usually take painkillers, especially combinations of different painkillers, you may damage your kidneys, **tell your doctor if you are already taking another painkiller before taking this medicine and your doctor will decide whether you should take this medicine.** This risk may be increased if you are dehydrated.

IF YOU TAKE MORE BRUFEN SYRUP THAN PRESCRIBED (AN OVERDOSE) you should contact a doctor or go to the nearest hospital casualty department **IMMEDIATELY** taking your syrup with you.

IF YOU FORGET TO TAKE YOUR BRUFEN SYRUP take it as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Never double up on a dose to make up for the one you have missed.

4. POSSIBLE SIDE EFFECTS OF BRUFEN SYRUP

As with all medicines, Brufen Syrup may cause side effects, although they are usually mild and not everyone will suffer from 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 syrup for the shortest amount of time necessary to control your symptoms.

STOP TAKING Brufen Syrup and seek immediate medical help if you experience:

- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.
- Signs of intestinal bleeding such as
 - Passing blood in your faeces (stools/motions)
 - Passing black tarry stools
 - Vomiting any blood or dark particles that look like coffee grounds

TELL YOUR DOCTOR AND STOP TAKING BRUFEN SYRUP IF YOU EXPERIENCE:

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction).
- Yellowing of the eyes and/or skin (jaundice).
- Severe sore throat with high fever (these may be symptoms of a condition known as agranulocytosis).
- Blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- Fluid retention e.g. swollen ankles (this may be a sign of kidney problems).
- Severe spreading skin rash (Stevens-Johnson Syndrome and erythema multiforme, symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness).

Medicines such as Brufen Syrup have been associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Medicines such as Brufen Syrup have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles

Blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen

Very rarely Brufen Syrup may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Brufen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

A burning feeling in the throat or mouth may happen briefly after taking this medicine.

Other side effects

Common (affects up to 1 in 10 people):

- rash
- feeling dizzy or tired
- stomach pain, indigestion, 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.
- passing black tarry stools
- passing blood in your faeces (stools/motions)
- vomiting any blood

Uncommon (affects up to 1 in a 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
- 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
- ringing in ears (tinnitus)
- sensation of feeling dizzy or spinning (vertigo)
- mouth ulcers
- serious allergic reaction which causes swelling of the face or throat

Rare (affects up to 1 in a 1000 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)
- serious allergic reaction which causes difficulty in breathing or dizziness
- severe sore throat with high fever (agranulocytosis)

Very rare (affects up to 1 in 10,000 people):

- liver failure
- heart failure
- heart attack
- 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'.
- high blood pressure

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

- worsening of ulcerative colitis or Crohn's Disease (inflammation of the colon)

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.

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

5. HOW SHOULD YOU STORE BRUFEN SYRUP?

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 25°C.
- Store in the original package to protect from light.
- Use within twelve months after first opening.
- If your doctor stops your treatment, take any leftover suspension back to the pharmacy for safe disposal.
- Do not take your suspension after the expiry date on the container. Take any suspension which is out of date back to the pharmacy.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. FURTHER INFORMATION ABOUT BRUFEN SYRUP

What Brufen Syrup contains

- Each 5ml of oral suspension contains 100mg ibuprofen.
- Brufen Syrup also contains the following: methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), sunset yellow (E110), sodium benzoate, glycerin, sorbitol solution 70% (non-crystallising) (E420), sucrose, citric acid monohydrate granular, agar powder, light kaolin, polysorbate 80, orange flavour (D717) and purified water.

What Brufen Syrup looks like and contents of the pack

- Brufen Syrup is an orange-coloured, orange-flavoured, suspension.
- Brufen Syrup is available in bottles of 200ml.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by AbbVie S.r.L., S.R. 148 Pontina km 52 snc, 04011 Campoverde di Aprilia (LT), Italy.

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Leaflet revision date: 04 July 2016

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- have any kind of stroke or think that you might be at risk of these conditions (e.g. if you have a family history of heart disease or stroke, high blood pressure, diabetes, high cholesterol or are a smoker).
- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
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- Is your child dehydrated? As there is a risk of kidney damage in dehydrated children and adolescents.

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- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- mifepristone
- any other ibuprofen, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including aspirin
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Other information about Brufen Syrup:

The syrup contains small amounts of glycerin (glycerol). In high doses, glycerin may sometimes cause headache, stomach upset and diarrhoea. As such, you should not take more than the stated dose unless your doctor advises you to. The syrup contains sucrose and therefore may be harmful to your teeth.

Pregnancy and breast-feeding: The use of Brufen Syrup whilst pregnant or breast feeding should be avoided. Brufen Syrup should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and Using Machines: Brufen Syrup may make you feel dizzy or drowsy. If it affects you in this way do not drive, operate machinery or do anything that requires you to be alert.

3. HOW SHOULD YOU TAKE BRUFEN SYRUP?

ALWAYS take Brufen Syrup exactly as your doctor has told you. If you are not sure refer to the label on the carton or check with your doctor or pharmacist. Ensure the bottle is thoroughly shaken before use. Take with or after food.

DOSAGE:

Adults and children over 12 years -The usual dosage is 4 to 6 spoonfuls (5 ml) taken three times a day. Your doctor may choose to increase or decrease this depending on what you are being treated for; but no more than 24 spoonfuls (120 ml/2400 mg) should be taken in one day.

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The doctor may choose to increase this dose in children with juvenile rheumatoid arthritis. This dose should not exceed 40mg/ kg bodyweight daily in divided doses.

You should avoid excessive use of painkillers. If you usually take painkillers, especially combinations of different painkillers, you may damage your kidneys, **tell your doctor if you are already taking another painkiller before taking this medicine and your doctor will decide whether you should take this medicine.** This risk may be increased if you are dehydrated.

IF YOU TAKE MORE BRUFEN SYRUP THAN PRESCRIBED (AN OVERDOSE) you should contact a doctor or go to the nearest hospital casualty department **IMMEDIATELY** taking your syrup with you.

IF YOU FORGET TO TAKE YOUR BRUFEN SYRUP take it as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Never double up on a dose to make up for the one you have missed.

4. POSSIBLE SIDE EFFECTS OF BRUFEN SYRUP

As with all medicines, Brufen Syrup may cause side effects, although they are usually mild and not everyone will suffer from 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 syrup for the shortest amount of time necessary to control your symptoms.

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- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.
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 - Passing blood in your faeces (stools/motions)
 - Passing black tarry stools
 - Vomiting any blood or dark particles that look like coffee grounds

TELL YOUR DOCTOR AND STOP TAKING BRUFEN SYRUP IF YOU EXPERIENCE:

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- Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction).
- Yellowing of the eyes and/or skin (jaundice).
- Severe sore throat with high fever (these may be symptoms of a condition known as agranulocytosis).
- Blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- Fluid retention e.g. swollen ankles (this may be a sign of kidney problems).
- Severe spreading skin rash (Stevens-Johnson Syndrome and erythema multiforme, symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness).

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Medicines such as Brufen Syrup have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles

Blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen

Very rarely Brufen Syrup may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Brufen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

A burning feeling in the throat or mouth may happen briefly after taking this medicine.

Other side effects

Common (affects up to 1 in 10 people):

- rash
- feeling dizzy or tired
- stomach pain, indigestion, 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.
- passing black tarry stools
- passing blood in your faeces (stools/motions)
- vomiting any blood

Uncommon (affects up to 1 in a 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
- 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
- ringing in ears (tinnitus)
- sensation of feeling dizzy or spinning (vertigo)
- mouth ulcers
- serious allergic reaction which causes swelling of the face or throat

Rare (affects up to 1 in a 1000 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)
- serious allergic reaction which causes difficulty in breathing or dizziness
- severe sore throat with high fever (agranulocytosis)

Very rare (affects up to 1 in 10,000 people):

- liver failure
- heart failure
- heart attack
- 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'.
- high blood pressure

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

- worsening of ulcerative colitis or Crohn's Disease (inflammation of the colon)

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.

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- Do not take your suspension after the expiry date on the container. Take any suspension which is out of date back to the pharmacy.
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6. FURTHER INFORMATION ABOUT IBUPROFEN SYRUP

What Ibuprofen Syrup contains

- Each 5ml of oral suspension contains 100mg ibuprofen.
- Ibuprofen Syrup also contains the following: methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), sunset yellow (E110), sodium benzoate, glycerin, sorbitol solution 70% (non-crystallising) (E420), sucrose, citric acid monohydrate granular, agar powder, light kaolin, polysorbate 80, orange flavour (D717) and purified water.

What Ibuprofen Syrup looks like and contents of the pack

- Ibuprofen Syrup is an orange-coloured, orange-flavoured, suspension.
- Ibuprofen Syrup is available in bottles of 200ml.

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Manufacturer

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