Package leaflet: Information for the patient
IBUPROFEN 100 mg/5 ml Oral Suspension
Ibuprofen 100 mg/5 ml

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to give Ibuprofen Oral Suspension to your child carefully to get the best results from it.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your child's symptoms worsen or do not improve after a few days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

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

1. What Ibuprofen is and what it is used for
Ibuprofen 100 mg/5 ml Oral Suspension ("Ibuprofen") contains ibuprofen as the active ingredient. This belongs to a group of medicines called **non-steroidal anti-inflammatory drugs (NSAIDs)**. Ibuprofen is given to children as a pain reliever for relief of mild to moderate muscular pain, headache, earache, sore throat, dental pain and backache. This medicine can also be used in minor injuries such as sprains and strains. It also reduces temperature in fever (e.g. post-immunisation fever), as well as other symptoms of cold and influenza.

2. What you need to know before you give Ibuprofen
Do NOT give this medicine if your child:
- is allergic to ibuprofen or any of the other ingredients of this medicine *(see Section 6 and end of Section 2: Important information about ingredients).*
- has had an allergic reaction or wheezing after taking aspirin or other non-steroidal anti-inflammatory painkillers. *(Symptoms of a rare allergic reaction are given under Section 4: Possible side effects).*
- has ever had a stomach ulcer or a history of bleeding into, or perforation of, the intestine especially after previous NSAID treatment (symptoms may include severe stomach pain or vomiting blood that contains dark particles)
- is taking any other non-steroidal anti-inflammatory painkillers (NSAIDs)
- has ever had severe kidney, heart or liver problems
- has an inherited intolerance to some sugars
- is less than 3 months old

If any of these apply, ask for advice from a doctor or pharmacist before giving this medicine.

Warnings and Precautions
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 Ibuprofen 100 mg/5 ml Oral Suspension 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. Stop immediately Ibuprofen 100 mg/5 ml Oral Suspension and contact immediately your doctor or medical emergencies if you notice any of these signs.

There is a risk of renal (kidney) impairment in dehydrated children.

If you are taking Ibuprofen 100 mg/5 ml Oral Suspension for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

You should discuss your child's treatment with your doctor or pharmacist before giving Ibuprofen 100 mg/5 ml Oral Suspension if your child:
- has high blood pressure, kidney or liver problems
- has asthma or diabetes
- has lupus or a mixed connective tissue disease
- has a chronic inflammatory intestinal disease such as ulcerative colitis or Crohn's disease or gastrointestinal bleeding
- has chickenpox
- has an infection - please see heading "Infections" below.

This product is intended for children aged between 3 months and 12 years. If you are an **adult** taking this product;
The above warnings and information apply, and in addition the following also applies:
- **Do NOT** take this product if you are taking aspirin at doses above 75 mg daily. If you are on low dose aspirin (up to 75 mg daily) speak to your doctor or pharmacist before you take this product.
- Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.
- Do not take if you are in the **last three months** of pregnancy.

Speak to your doctor or pharmacist before taking if;
- you are in the **first six months** of pregnancy
- you are elderly
- you are trying to get pregnant. Ibuprofen belongs to a group of medicines which may **impair fertility** in women. This 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
- 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 or 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.

Infections
Ibuprofen 100 mg/5 ml Oral Suspension may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen 100 mg/5 ml Oral Suspension 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.

The use of painkillers for a long period of time has been linked to headaches in some patients, a condition called medication overuse headache (MOH). Patients who have frequent or daily headaches despite (or because of) the regular use of pain killers should not be treated with increased doses of Ibuprofen 100 mg/5 ml Oral Suspension. Tell your doctor if you have been having headaches while taking this medicine.

Other medicines and Ibuprofen 100 mg/5 ml Oral Suspension
Please tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription. Ibuprofen 100 mg/5 ml Oral Suspension may affect or be affected by some medicines. For example:
- **Diuretics** (drugs to help you pass water)
- Medicines that are anticoagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- **Lithium** or **Selective serotonin reuptake inhibitors** (SSRI's e.g. Fluoxetine) (used to treat mood disorders)
- **Methotrexate** (used to treat rheumatoid arthritis, psoriasis and some cancers)
- **Zidovudine** (used to treat HIV)
- **Corticosteroids** (anti-inflammatory drugs, such as Hydrocortisone)
- **Cardiac glycosides** (drugs used in the treatment of heart problems, such as Digoxin)
- **Ciclosporin** or **Tacrolimus** (used to suppress the body's immune system)
- **Mifepristone** (used to terminate a pregnancy)
- **Quinolone antibiotics** (used to treat a wide range of infections e.g. Ciprofloxacin)
- **Aminoglycosides** (type of antibiotics)
- **Cholestyramines** (drugs used to lower cholesterol)
- **Sulphonylureas** (used to treat diabetes e.g. Glibenclamide)
- any other **Ibuprofen preparations**, including those you can buy without a prescription
- **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).

Some other medicines may also affect or be affected by the treatment of Ibuprofen 100 mg/5 ml. You should therefore always seek the advice of your child's doctor or pharmacist before you give Ibuprofen 100 mg/5 ml Oral Suspension with other medicines.

Ibuprofen 100 mg/5 ml Oral Suspension and alcohol:
Ibuprofen may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol while taking this medicine might make these side effects worse.

Pregnancy and breast-feeding
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 for 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 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.

Driving and using machines
Ibuprofen 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.

Important information about some of the ingredients of this medicine
- **Maltitol (E965)**, may have a mild laxative effect. If your child has an intolerance to some sugars, contact your doctor before giving this medicine.
- **Sodium methyl hydroxybenzoate (E219) and Sodium propyl hydroxybenzoate (E217)**, may cause allergic reactions (possibly delayed).
- **Propylene glycol (E1520).** This medicine contains 5.2 mg propylene glycol in each 5 ml which is equivalent to 0.832 mg/g.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dose, that is to say essentially 'sodium-free'.

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3. How to give Ibuprofen
Shake the bottle well before measuring the dose. A double-ended measuring spoon is provided to ensure accuracy. The small spoon measures a 2.5 ml dose and the larger spoon measures 5 ml.

This medicine should **NOT** be given if your child weighs less than 5 kg. The usual daily dose in children is 20 mg per kg of bodyweight in divided doses, **every 6 to 8 hours if required. Leave at least 4 hours between doses.**
For short term use only. 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).

WARNING: DO NOT EXCEED THE STATED DOSE

DOSAGE: Children (A spoon is provided to measure doses of 2.5 ml or 5 ml)		
3 - 6 months (weighing over 5 kg)	2.5 ml 3 times a day	Do not give for more than 24 hours.
6 months – 1 year	2.5 ml 3 to 4 times a day	Do not give to children aged 6 months and older for more than 3 days.
1 year – 4 years	5 ml 3 times a day	
4 years – 7 years	7.5 ml 3 times a day	
7 years – 12 years	10 ml 3 times a day	
Do not give to babies under 3 months		

For infants aged 3-5 months medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist.

If in children aged from 6 months and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Post-immunisation fever: One small spoonful (2.5 ml), followed by another small spoonful (2.5 ml) 6 hours later if necessary. No more than 2 doses should be given in 24 hours. If fever is not reduced, consult a doctor.

If you forget to give this medicine
If you forget to give a dose, give it as soon as you remember, unless it is almost time for the next dose. Never give a double dose to make up for the missed dose.

If you give more medicine than you should
If your child or someone else accidentally takes more Ibuprofen than the stated dose (an overdose), always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken and take the bottle with you if you can.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding, diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also, agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. 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. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

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

You should STOP giving Ibuprofen and seek advice from your doctor if your child experiences a very rare allergic reaction, including skin rashes, increased sensitivity to light, swelling of the face and tongue, inflammation of the blood vessels, fever or shock. Skin and mucous membrane reactions may also occur.

If your child suffers from the following, stop giving the medicine and seek immediate medical help:
- Passing blood in their faeces (stools/motions)
- Passing black tarry stools
- Vomiting blood or dark particles that look like ground coffee
- Stiff neck, intolerance to bright light, headache, nausea, vomiting, fever and disorientation
- 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)
- 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. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).
- 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 the medicine and tell your doctor immediately:
- Unexplained stomach pain, indigestion, heartburn, feeling sick and/or vomiting
- Unexplained wheezing, shortness of breath, skin rash (which may be severe and include blistering or peeling of the skin), itching or bruising, light-headedness, racing of the heart or fluid retention e.g. swollen ankles, not passing enough urine
- loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations)
- Yellowing of the eyes and/or skin
- Severe sore throat with high fever or unexplained bleeding, bruising and tiredness.
- Liver, kidney problems or difficulty urinating.

This medicine have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

This medicine have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles.

Blood disorders such as reduction in blood cells and platelet counts - the first signs are: sore throat with high fever, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin.

Ibuprofen 100 mg/5 ml Oral Suspension, 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 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Liver problems such as inflammation of the liver, reduced liver function and yellowing of the eyes and/or skin (jaundice) or severe skin reactions may occur rarely with ibuprofen.

Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated.

Other unusual effects may include:
Common (may affect up to 1 in 10 people):
- Feeling dizzy or tired
- Flatulence, diarrhoea, 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):
- Drowsiness
- Anxiety
- Feeling a tingling sensation or 'pins and needles'
- Insomnia
- Hives
- Skin becomes sensitive to light
- Hearing impairment
- Sneezing, blocked, itchy or runny nose (rhinitis)
- Stomach or gut ulcer, hole in the wall of the digestive tract
- Inflammation of your stomach lining
- Ringing in ears (tinnitus)
- Sensation of spinning (vertigo)
- Mouth ulcer.

Rare (may affect up to 1 in 1,000 people):
- Feeling depressed or confused.

Very rare (may affect up to 1 in 10,000 people):
- Inflammation of the pancreas.

Not known (frequency cannot be estimated from the available data):
- Skin becomes sensitive to light
- Fixed drug rash, which may progress to generalised blistering lesions.

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. How to store Ibuprofen
Keep this medicine out of the sight and reach of children. Do not use after the expiry date shown on the bottle. Do not store above 25°C.

6. Contents of the pack and other information
What Ibuprofen contains:
The **active ingredient** is ibuprofen 100 mg per 5 ml
The **other ingredients** are: glycerol (E422), xanthan gum, maltitol (E965), polysorbate 80, saccharin sodium (E954), citric acid monohydrate, sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217), purified water and strawberry flavour (contains propylene glycol).

What Ibuprofen looks like and contents of the pack:
Ibuprofen is a sugar free, colour-free and strawberry flavoured oral suspension.
This medicine comes in amber glass bottles or polyethylene bottles of: 50 ml, 100 ml, 150 ml or 200 ml with a child-resistant closure.

Marketing Authorisation Holder
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

Manufacturer
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland or
CP Pharmaceuticals Ltd., Ash Road North, Wrexham, LL13 9UF, United Kingdom.

PL Number: 04917/0044
This leaflet was prepared in August 2024

23LF02101PW

Artwork Code:	23LF02101PW	Font:	Helvetica 8pt
Date	08/08/24	Dimensions:	420 x 190 mm
Printing: Black Non-Printing: Keyline, Text Free Area			Version: 1
Other information: Previous code - 23LF02069PW Regulatory Safety Updates			

Package leaflet: Information for the patient
IBUPROFEN 100 mg/5 ml Oral Suspension
Ibuprofen 100 mg/5 ml

Read all of this leaflet carefully before you start giving this medicine to your child.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's symptoms.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- You must contact a doctor if your child's symptoms worsen or do not improve after a few days.

What is in this leaflet:

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

1. What Ibuprofen is and what it is used for
Ibuprofen 100 mg/5 ml Oral Suspension ("Ibuprofen") contains ibuprofen as the active ingredient. This belongs to a group of medicines called **non-steroidal anti-inflammatory drugs (NSAIDs)**. Ibuprofen is given to children as a pain reliever for relief of mild to moderate muscular pain, headache, earache and dental pain. This medicine can also be used in soft tissue injuries such as sprains and strains. It also reduces temperature in fever (e.g. post-immunisation fever), as well as other symptoms of cold and influenza. Ibuprofen can be used to relieve menstrual (period) pain, neuralgia (acute nerve pain, often of the face) and to reduce pain and swelling after an operation. It also reduces pain and inflammation in conditions of the bones and joints such as rheumatoid arthritis (including juvenile rheumatoid arthritis, or Still's disease), inflammation of the spinal joints (ankylosing spondylitis), osteoarthritis and other joint conditions. For muscle and tendon problems, it can be used for frozen shoulder (capsulitis), pain and tenderness in joint movement (bursitis), inflammation of tendons (tendonitis and tenosynovitis), and low back pain.

2. What you need to know before you give Ibuprofen
Do NOT give this medicine if your child:
- is allergic to ibuprofen or any of the other ingredients of this medicine *(see Section 6 and end of Section 2: Important information about ingredients).*
- has had an allergic reaction or wheezing after taking aspirin or other non-steroidal anti-inflammatory painkillers. *(Symptoms of a rare allergic reaction are given under Section 4: Possible side effects).*
- has ever had a stomach ulcer or a history of bleeding into, or perforation of, the intestine especially after previous NSAID treatment
- is taking any other non-steroidal anti-inflammatory painkillers (NSAIDs)
- has ever had severe kidney, heart or liver problems
- has an inherited intolerance to some sugars
- is less than 3 months old

If any of these apply, ask for advice from a doctor or pharmacist before giving this medicine.

Warnings and Precautions
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 Ibuprofen 100 mg/5 ml Oral Suspension 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. Stop immediately Ibuprofen 100 mg/5 ml Oral Suspension and contact immediately your doctor or medical emergencies if you notice any of these signs.

There is a risk of renal (kidney) impairment in dehydrated children.

If you are taking Ibuprofen 100 mg/5 ml Oral Suspension for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

You should discuss your child's treatment with your doctor or pharmacist before giving Ibuprofen 100 mg/5 ml Oral Suspension if your child:
- has high blood pressure, kidney or liver problems
- has asthma or diabetes
- has lupus or a mixed connective tissue disease
- has a chronic inflammatory intestinal disease such as ulcerative colitis or Crohn's disease or gastrointestinal bleeding
- has chickenpox
- has an infection - please see heading "Infections" below.

This product is intended for children aged between 3 months and 12 years. If you are an **adult** taking this product;
The above warnings and information apply, and in addition the following also applies:
- **Do NOT** take this product if you are taking aspirin at doses above 75 mg daily. If you are on low dose aspirin (up to 75 mg daily) speak to your doctor or pharmacist before you take this product.
- Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.
- Do not take if you are in the **last three months** of pregnancy.

Speak to your doctor or pharmacist before taking if;
- you are in the **first six months** of pregnancy
- you are elderly
- you are trying to get pregnant. Ibuprofen belongs to a group of medicines which may **impair fertility** in women. This 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
- 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 or 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.

Infections
Ibuprofen 100 mg/5 ml Oral Suspension may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen 100 mg/5 ml Oral Suspension 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.

The use of painkillers for a long period of time has been linked to headaches in some patients, a condition called medication overuse headache (MOH). Patients who have frequent or daily headaches despite (or because of) the regular use of pain killers should not be treated with increased doses of Ibuprofen 100 mg/5 ml Oral Suspension. Tell your doctor if you have been having headaches while taking this medicine.

Other medicines and Ibuprofen 100 mg/5 ml Oral Suspension
Please tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription. Ibuprofen 100 mg/5 ml Oral Suspension may affect or be affected by some medicines. For example:
- **Diuretics** (drugs to help you pass water)
- Medicines that are anticoagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- **Lithium** or **Selective serotonin reuptake inhibitors** (SSRI's e.g. Fluoxetine) (used to treat mood disorders)
- **Methotrexate** (used to treat rheumatoid arthritis, psoriasis and some cancers)
- **Zidovudine** (used to treat HIV)
- **Corticosteroids** (anti-inflammatory drugs, such as Hydrocortisone)
- **Cardiac glycosides** (drugs used in the treatment of heart problems, such as Digoxin)
- **Ciclosporin** or **Tacrolimus** (used to suppress the body's immune system)
- **Mifepristone** (used to terminate a pregnancy)
- **Quinolone antibiotics** (used to treat a wide range of infections e.g. Ciprofloxacin)
- **Aminoglycosides** (type of antibiotics)
- **Cholestyramines** (drugs used to lower cholesterol)
- **Sulphonylureas** (used to treat diabetes e.g. Glibenclamide)
- any other **Ibuprofen preparations**, including those you can buy without a prescription
- **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).

Some other medicines may also affect or be affected by the treatment of Ibuprofen 100 mg/5 ml. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen 100 mg/5 ml Oral Suspension with other medicines.

Ibuprofen 100 mg/5 ml Oral Suspension and alcohol:
Ibuprofen may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol while taking this medicine might make these side effects worse.

Pregnancy and breast-feeding
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 for 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 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.

Driving and using machines
Ibuprofen 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.

Important information about some of the ingredients of this medicine
- **Maltitol (E965)**, may have a mild laxative effect. If your child has an intolerance to some sugars, contact your doctor before giving this medicine.
- **Sodium methyl hydroxybenzoate (E219) and Sodium propyl hydroxybenzoate (E217)**, may cause allergic reactions (possibly delayed).
- **Propylene glycol (E1520).** This medicine contains 5.2 mg propylene glycol in each 5 ml which is equivalent to 0.832 mg/g.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dose, that is to say essentially 'sodium-free'.

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3. How to give Ibuprofen
Shake the bottle well before measuring the dose. A double-ended measuring spoon is provided to ensure accuracy. The small spoon measures a 2.5 ml dose and the larger spoon measures 5 ml.

This medicine should **NOT** be given if your child weighs less than 5 kg. The usual daily dose in children is 20 mg per kg of bodyweight in divided doses, **every 6 to 8 hours if required. Leave at least 4 hours between doses.**
For short term use only. 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).

WARNING: DO NOT EXCEED THE STATED DOSE

DOSAGE: Children (A spoon is provided to measure doses of 2.5 ml or 5 ml)		
3 - 6 months (weighing over 5 kg)	2.5 ml 3 times a day	Do not give for more than 24 hours.
6 months – 1 year	2.5 ml 3 to 4 times a day	Do not give to children aged 6 months and older for more than 3 days.
1 year – 4 years	5 ml 3 times a day	
4 years – 7 years	7.5 ml 3 times a day	
7 years – 12 years	10 ml 3 times a day	
Do not give to babies under 3 months		

For infants aged 3-5 months medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist.

If in children aged from 6 months and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Post-immunisation fever: One small spoonful (2.5 ml), followed by another small spoonful (2.5 ml) 6 hours later if necessary. No more than 2 doses should be given in 24 hours. If fever is not reduced, consult a doctor.

Juvenile Rheumatoid Arthritis: Your doctor will work out the dose to be taken, depending on the weight of your child.

If you forget to give this medicine
If you forget to give a dose, give it as soon as you remember, unless it is almost time for the next dose. Never give a double dose to make up for the missed dose.

If you give more medicine than you should
If your child or someone else accidentally takes more Ibuprofen than the stated dose (an overdose), always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken and take the bottle with you if you can.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding, diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also, agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. 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. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

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

You should STOP giving Ibuprofen and seek advice from your doctor if your child experiences a very rare allergic reaction, including skin rashes, increased sensitivity to light, swelling of the face and tongue, inflammation of the blood vessels, fever or shock. Skin and mucous membrane reactions may also occur.

If your child suffers from the following, stop giving the medicine and seek immediate medical help:
- Passing blood in their faeces (stools/motions)
- Passing black tarry stools
- Vomiting blood or dark particles that look like ground coffee
- Stiff neck, intolerance to bright light, headache, nausea, vomiting, fever and disorientation.
- 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)
- 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. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)
- 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 the medicine and tell your doctor:
- Unexplained stomach pain, indigestion, heartburn, feeling sick and/or vomiting
- Unexplained wheezing, shortness of breath, skin rash (which may be severe and include blistering or peeling of the skin), itching or bruising, light-headedness, racing of the heart or fluid retention e.g. swollen ankles, not passing enough urine
- loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations)
- Yellowing of the eyes and/or skin
- Severe sore throat with high fever or unexplained bleeding, bruising and tiredness.
- Liver, kidney problems or difficulty urinating.

This medicine have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

This medicine have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles.

Blood disorders such as reduction in blood cells and platelet counts - the first signs are: sore throat with high fever, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin.

Ibuprofen 100 mg/5 ml Oral Suspension, 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 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Liver problems such as inflammation of the liver, reduced liver function and yellowing of the eyes and/or skin (jaundice) or severe skin reactions may occur rarely with ibuprofen.

Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated.

Other unusual effects may include:
Common (may affect up to 1 in 10 people):
- Feeling dizzy or tired
- Flatulence, diarrhoea, 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):
- Drowsiness
- Anxiety
- Feeling a tingling sensation or 'pins and needles'
- Insomnia
- Hives
- Skin becomes sensitive to light
- Hearing impairment
- Sneezing, blocked, itchy or runny nose (rhinitis)
- Stomach or gut ulcer, hole in the wall of the digestive tract
- Inflammation of your stomach lining
- Ringing in ears (tinnitus)
- Sensation of spinning (vertigo)
- Mouth ulcer.

Rare (may affect up to 1 in 1,000 people):
- Feeling depressed or confused.

Very rare (may affect up to 1 in 10,000 people):
- Inflammation of the pancreas.

Not known (frequency cannot be estimated from the available data):
- Skin becomes sensitive to light
- Fixed drug rash, which may progress to generalised blistering lesions.

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. How to store Ibuprofen
Keep this medicine out of the sight and reach of children. Do not use after the expiry date shown on the bottle. Do not store above 25°C.

6. Contents of the pack and other information
What Ibuprofen contains:
The **active ingredient** is ibuprofen 100 mg per 5 ml
The **other ingredients** are: glycerol (E422), xanthan gum, maltitol (E965), polysorbate 80, saccharin sodium (E954), citric acid monohydrate, sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217), purified water and strawberry flavour (contains propylene glycol).

What Ibuprofen looks like and contents of the pack:
Ibuprofen is a sugar free, colour-free and strawberry flavoured oral suspension, which comes in a 500 ml HDPE bottle with a tamper evident cap.

Marketing Authorisation Holder
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

Manufacturer
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland or
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PL Number: 04917/0044
This leaflet was prepared in August 2024

23LF02102CL

Artwork Code:	23LF02102CL	Font:	Helvetica 8pt
Date	08/08/24	Dimensions:	420 x 190 mm
Printing: Black Non-Printing: Keyline, Text Free Area			Version: 1
Other information: Previous code - 23LF02070CL Regulatory Safety Updates			