Package leaflet: Information for the patient

Brupro for Children 100 mg/5 ml oral suspension
ibuprofen

Read all of this leaflet carefully before you use this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- **You must talk to a doctor if you or your child do not feel better or if you or your child feel worse after 3 days (<u>not later than 24 hours in case of infants 3 to 5 months of age</u>).**

What is in this leaflet

1. What Brupro for Children is and what it is used for

The active ingredient (which makes this medicine work) is ibuprofen which is a non-steroidal-anti-inflammatory (NSAID) painkiller. Ibuprofen is used as an analgesic (painkiller) for the relief of teething and toothache pain, earache, headache, muscular minor aches and sprains, sore throats and cold and flu symptoms. Brupro for Children also reduces a high temperature (fever).

2. What you need to know before you use Brupro for Children

Do not give Brupro for Children to children who:

- **are less than 3 months old or weigh less than 5 kg.**
- are **allergic to ibuprofen or other similar painkillers (NSAIDs)** or to any of the other ingredients of this medicine (listed in section 6)
- have ever suffered from shortness of breath, asthma, a runny nose, swelling on their face and/or hands or hives after using acetylsalicylic acid **(aspirin)** or **other similar painkillers (NSAIDs)**
- have ever had **gastrointestinal bleeding or perforation**, related to previous use of NSAIDs
- currently have or have had **recurrent stomach/duodenal ulcers (peptic ulcers) or bleeding** (two or more episodes of proven ulceration or bleeding)
- have **severe liver** or **severe kidney failure**
- have **severe heart failure**
- have **bleeding of the brain** (cerebrovascular bleeding) or **other active bleeding**
- suffer from **blood clotting disorders** as ibuprofen may increase bleeding time
- have **unclarified blood-forming disturbances**
- have **severe dehydration** (caused by vomiting, diarrhoea or lack of drinking).

Do not take if you are in the **last 3 months of pregnancy.**

Warnings and precautions

Talk to your doctor or pharmacist before using this medicinal product if your child

- has certain **hereditary blood formulation disorders** (e.g. acute intermittent porphyria)
- suffers from blood **coagulation disturbances**
- has certain **diseases of the skin** (e.g., systemic lupus erythematosus (SLE) or mixed connective tissue disease)
- has or has ever had **bowel disease** (ulcerative colitis or Crohn's disease) as these conditions may be worsened (see section 4 "possible side effects")
- has ever had or currently has **high blood pressure** and/or **heart failure**
- has **kidney problems** (reduced renal function)
- has **liver problems**. In prolonged administration of Brupro for Children, regular checking of the liver values, the kidney function, as well as of the blood count, is required.
- is taking other medicines which could increase the **risk of ulcers forming or bleeding**, such as oral corticosteroids (anti-inflammatories such as prednisolone), medicines for thinning the blood (such as warfarin), selective serotonin-reuptake inhibitors (a medicine for depression) or anti-platelet agents (such as acetylsalicylic acid)
- is taking **another NSAID medicine** (including COX-2 inhibitors such as celecoxib or etoricoxib) as taking these together should be avoided (see section "taking other medicines")
- has or has had **asthma or allergic diseases,** as shortness of breath may occur
- suffers from **hay fever, nasal polyps or chronic obstructive respiratory disorders,** as an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so called analgesic asthma), Quincke's oedema or hives.
- has **chicken pox** (varicella) - it is advisable to avoid use of Brupro for Children
- has just undergone **major surgery,** as medical surveillance is required
- is **dehydrated,** as there is a risk of renal impairment in dehydrated children
- has an **infection** – please see the heading 'Infections' below. NSAIDs may mask symptoms of infection and fever.

Infections

Brupro for Children may hide signs of infections such as fever and pain. It is therefore possible that Brupro for Children 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 or give this medicine while you or your child have an infection and symptoms of the infection persist or worsen, consult a doctor without delay.

Skin reactions

Serious skin reactions (such as Steven-Johnson syndrome) have been reported very rarely in association with the use of NSAIDs. The use of Brupro for Children should be stopped immediately at the first appearance of skin rash, mucosal lesions, or any other signs of allergic reactions

You should discuss your treatment with your doctor or pharmacist before taking Brupro for Children 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 attach "TIA")
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Consult a doctor before using Brupro for Children if any of the above mentioned conditions affect your child.

Other medicines and Brupro for Children
Tell your doctor or pharmacist if your child is using or has recently used or might use any other medicines.

Brupro for Children may affect or be affected by some other medicines. For example:
- Medicines that are anti-coagulants (i.e. thin blood / prevent clotting, e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, betablockers such as atenolol, angiotensin-II receptor antagonists such as losartan).

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell them if your child is taking:
- **Other NSAIDs**, including COX-2 inhibitors (this may increase the risk of side effects)
- **Digoxin** (for heart problems)
- **Glucocorticoids** (an anti-inflammatory drug)
- **Anti-platelet agents**, since this may increase the risk of bleeding
- **Aspirin (acetylsalicylic acid)** (low dose) since the blood thinning effect may be impaired
- **Medicines for thinning the blood** (such as warfarin)
- **Phenytoin** (for epilepsy)
- **Selective serotonin re-uptake inhibitors (SSRI)** (medicines used for depression)
- **Lithium** (for mood disorders)
- **Probenecid and sulfinpyrazones** (medicines for gout)
- **Medicines for high blood pressure and water tablets** (to help pass water)
- **Potassium sparing diuretics** (e.g. amiloride, potassium canrenoate, spironolactone, triamterene)
- **Methotrexate** (a medicine for cancer or rheumatism)
- **Tacrolimus and ciclosporin** (to prevent organ rejection after transplant)
- **Zidovudine** (a medicine for treating HIV/AIDS)
- **Sulfonylureas** (anti-diabetic medicines)
- **Quinolone antibiotics** (used to treat infections)
- **Voriconazole and fluconazole** (for treating fungal infections)
- **Baclofen** (used to treat muscle spasm)
- **Ritonavir** (a medicine for treating HIV/AIDS)
- **Aminoglycosides** (a type of antibiotic)
- **Mifepristone** now or in the last 12 days

Brupro for Children with alcohol
You should not drink alcohol while using Brupro for Children. Some side effects, such as those affecting the gastrointestinal tract or the central nervous system can be more likely when alcohol is taken at the same time as Brupro for Children.

If you are an adult taking this medicine
The warnings and information given in this section apply and in addition the following:

Pregnancy, breast-feeding and fertility:
If you are pregnant or breast-feeding, 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 use this medicine if you are in the last 3 months of pregnancy. Avoid the use of this medicine in the first 6 months of pregnancy unless your doctor advises you otherwise.

Breast-feeding
Only small amounts of ibuprofen and its decomposition products pass into breast milk. Brupro for Children may be used during breast-feeding, if it is used at the recommended dose and for the shortest possible time

Fertility
Brupro for Children belongs to a group of medicines (NSAIDs) which may impair fertility in women. This effect is reversible on stopping the medicine.

Other warnings
- Medicines such as Brupro for Children 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.
- **Elderly:** The elderly are more prone to side effects, particularly those relating to the stomach and bowel, which may be fatal. See Section 4 "Possible side effects" for more information. Patients with a history of gastrointestinal toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment.
- Undesirable effects may be minimised by using the minimum effective dose for the shortest duration
- In general, the habitual use of (several sorts of) analgesics can lead to lasting **severe kidney problems**. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore, it should be avoided.
- Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained, and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications
- **Gastrointestinal** bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any-time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events. When gastrointestinal bleeding or ulceration occurs, the treatment should be stopped immediately. The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 2 "Do not give Brupro for Children") and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for those patients, and also those requiring concomitant low-dose aspirin, or other drugs likely to increase gastrointestinal risk.

Driving and using machines
For short-term use - this medicine has no or negligible influence on the ability to drive and use machinery.

Brupro for Children contains sorbitol, propylene glycol, sodium, sodium benzoate and ethanol
This medicine contains 140 mg sorbitol in each 5 ml dose. Sorbitol is a source of fructose. If your doctor has told you that your child has an intolerance to some sugars or if they 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 your child receives this medicine.

This medicine contains 50 mg propylene glycol in each 5 ml dose.

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

This medicine contains 10 mg sodium benzoate in each 5 ml dose.

This medicine contains 5.25 mg of alcohol (ethanol) in each 5 ml dose. The amount in 5 ml of this medicine is equivalent to less than 0.1 ml beer or 0.1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Brupro for Children

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

How much medicine to use

DO NOT give to babies under 3 months or babies weighing less than 5kg.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you or your child has an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Duration of treatment
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 6 months and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

The recommended dose is:

Age	Dose
3 months – 6 months **5 - 7.6 kg**	**One 2.5 ml dose 3 times in 24 hours**
6 months – 12 months **7.7 – 9 kg**	**One 2.5 ml dose 3 times in 24 hours**
1 year – 3 years **10 – 16 kg**	**One 5 ml dose 3 times in 24 hours**
4 years – 6 years **17 – 20 kg**	**One 7.5 ml (5 ml + 2.5 ml) dose 3 times in 24 hours**
7 years to 9 years **21 – 30 kg**	**One 10 ml (5 ml + 5 ml) dose 3 times in 24 hours**
10 years to 12 years **31 – 40 kg**	**One 15 ml (5 ml + 5 ml + 5 ml) dose 3 times in 24 hours**
• Do not dose more frequently than at 6 hour intervals. • For **Short-term use only**	

WARNING:
Do not exceed the stated dose

For patients with sensitive stomachs it is recommended that Brupro for Children is taken during a meal.

Always shake the bottle thoroughly before use.
To remove the cap, push it down and turn it anti-clockwise. For children with sensitive stomachs the product can be taken during a meal. Use either the measuring spoon or the 5ml dosing syringe provided in the pack to ensure accurate dosing.

Using the dosing syringe
Push the syringe into the plug (hole) in the neck of the bottle.
To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the

plunger down drawing the medicine to the correct mark on the syringe. See section "How much medicine to use".
Turn the bottle the right way up, remove the syringe from the bottle plug by gently twisting the syringe. Place the end of the syringe into the child's mouth and gently press the plunger down to slowly and gently release the medicine.

If you take more Brupro for Children than you should:
If you have taken more Brupro for Children 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), gastrointestinal bleeding, headache, ringing in the ears, confusion, nystagmus (shaky eye movement) or more rarely diarrhoea. In addition, at high doses, vertigo, blurred vision, low blood pressure, excitation, disorientation, coma, hyperkalaemia (raised blood potassium levels), increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, exacerbation of asthma in asthmatics, 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 give Brupro for Children
Do not take or give a double dose to make up for a forgotten dose. If you do forget to take or give a dose, take or give it as soon as you remember and then take or give the next dose according to the dosing interval detailed above. **Do not give a double dose.**

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

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. Although side effects are uncommon, your child may get one of the know side effects of NSAIDs. If they do, or if you have concerns, stop giving this medicine to your child and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects.

STOP USING this medicine and seek immediate medical help if your child develops:

- **Signs of intestinal bleeding** such as: severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds
- **Signs of rare but serious allergic reactions** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, racing heart, drop in blood pressure leading to shock. These can happen even on first use of this medicine. If any of these symptoms occur, call a doctor at once.
- **Severe skin reactions** such as rashes covering the whole body, peeling, blistering or flaking of skin.
- **Signs of aseptic meningitis** with neck stiffness, headache, feeling sick, being sick, fever or clouding of consciousness. Patients with autoimmune disorders (systemic lupus erythematosus, mixed connective-tissue disease) may be more likely to be affected.

Tell your doctor if your child has any of the following side effects, they become worse or you notice any effects not listed.

Common (may affect up to 1 in 10 people)

- Stomach and intestinal complaints such as acid/heartburn, stomach pain and nausea, indigestion diarrhoea, vomiting, flatulence (wind) and constipation..

Uncommon (may affect up to 1 in 100 people)

- Gastrointestinal ulcers, perforation or bleeding, inflammation of the mucous membrane of the mouth with ulceration, worsening of existing bowel disease (colitis or Crohn's disease), gastritis
- Headache, dizziness, sleeplessness, agitation, irritability or tiredness
- Visual disturbances
- Various skin rashes
- Hypersensitivity reactions with hives and itch.

Rare (may affect up to 1 in 1000 people)

- Tinnitus (ringing in the ears)
- Increased urea concentrations in blood, pain in the flanks and/or the abdomen, blood in the urine and a fever may be signs of damage to kidneys (papillary necrosis)
- Increased uric acid concentrations in the blood
- Anaemia (Decreased haemoglobin levels).

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

- Oesophagitis (inflammation of the lining of the oesophagus), pancreatitis (inflammation of the pancreas, which cause severe pain in the abdomen and back) and formation of intestinal diaphragm-like strictures
- Heart failure, heart attack and swelling in the face or hands (oedema)
- Passing less urine than normal and swelling (especially in patients with high blood pressure or reduced kidney function), swelling (oedema) and cloudy urine (nephrotic syndrome), inflammatory kidney disease (interstitial nephritis) that may lead to acute kidney failure. If one of the above mentioned symptoms occur or if you have a general miserable feeling, stop taking Brupro for Children and consult your doctor immediately as these could be first signs of kidney damage or kidney failure
- Psychotic reactions, depression
- High blood pressure, vasculitis
- Palpitations
- Liver dysfunction, (first signs could be yellowing of the eyes, pale stools, dark urine, discolouration of the skin) especially during long-term treatment, liver failure, acute inflammation of the liver (hepatitis)
- Blood disorders. First signs include: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding. In such cases stop this medicine immediately and consult a doctor.
- Severe skin infections and soft tissue complications during chicken pox (varicella) infection
- Worsening of infection-related inflammations (e.g. necrotising fasciitis) associated with the use of certain painkillers (NSAIDs) has been described. If signs of an infection occur or get worse, you must go to the doctor without delay. It is to be investigated whether there is an anti-infective/antibiotic therapy
- Symptoms of aseptic meningitis with stiff neck, headache, nausea, vomiting, fever or clouding of consciousness have been observed when using ibuprofen. Patients with autoimmune disorders (SLE, mixed connective tissue disorder) may be more likely to be affected. Contact a doctor at once if these occur
- Severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-Johnson syndrome, erythema, multiforme, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia).

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

- Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea
- 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). Medicines such as this may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.
- 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). Stop using Brupro for Children if you or your child develop these symptoms and seek medical attention immediately.

Reporting 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 HPRA Pharmacovigilance, website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Brupro for Children

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 label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first opening use within 3 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 Brupro for Children contains

The active substance is ibuprofen. Each 5 ml of oral suspension contains 100 mg ibuprofen.

The other ingredients are propylene glycol (E 1520), glycerol (E 422), xanthan gum, citric acid, sodium benzoate (E 211), polysorbate 80, saccharin sodium, sorbitol liquid (E 420), sodium citrate, orange flavour (containing ethanol) and purified water.

What Brupro for Children looks like and contents of the pack

Brupro for Children is a white or almost white oral suspension. It is presented in glass bottles with a plastic child-resistant closure containing 100 ml or 200 ml oral suspension. Each pack contains one bottle of 100 ml or 200 ml oral suspension and either a measuring spoon or oral syringe. Not all pack sizes may be marketed.

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This leaflet was last revised in XX/YYYY.