

## Package leaflet: Information for the user

### **Brupro for Children 100 mg/5ml Oral Suspension**

For children from 5 kg body weight (3 months) to 39 kg body weight (11 years)

Ibuprofen

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### **What is in this leaflet:**

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

## **1 What Brupro for Children is and what it is used for**

Brupro for Children is a medicine that relieves pain and lowers fever (non-steroidal anti-inflammatory drug, NSAID).

Brupro for Children is used for the short-term symptomatic treatment of:

- mild to moderate pain
- fever.

Brupro for Children is for use in children from 5 kg body weight (3 months) to 39 kg body weight (11 years).

## **2 What you need to know before you take Brupro for Children**

### **Do not take Brupro for Children**

- if the child to be treated is allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- if the child to be treated has a history of shortness of breath, asthma attacks, swelling of the inner lining of the nose (rhinitis) or skin reactions (swelling or urticaria) after taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- in unclarified blood-formation disturbances.
- in active or history of recurrent stomach/duodenal ulcers (peptic ulcers) or bleeding (two or more distinct episodes of proven ulceration or bleeding).

- in a history of gastro-intestinal bleeding or perforation, related to previous NSAIDs therapy.
- in cerebrovascular bleeding or other active bleeding
- if the child to be treated has severe impairment of liver or kidney function or severe heart failure.
- in severe dehydration (from vomiting, diarrhoea or insufficient fluid intake).
- in the last three months of pregnancy.

### **Warnings and precautions**

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

#### Safety in the gastrointestinal tract

The use of Brupro for Children at the same time as NSAIDs, including so-called COX-2 inhibitors (cyclooxygenase-2 selective inhibitors) should be avoided.

Elderly patients: The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

Bleeding of the gastrointestinal tract, ulcers and perforation: Bleeding of the gastrointestinal tract, ulcers and perforation, in some cases fatal, have been reported during treatment with all NSAIDs. Such effects occurred at any time during therapy, with or without warning symptoms or a previous history of serious events in the gastrointestinal tract.

The risk of developing gastrointestinal bleeding, ulcers and perforation is higher with the increasing NSAID doses and is higher in patients with a history of ulcer, especially with complications of bleeding or perforation (see section 2) and in elderly patients. These patients should start treatment at the lowest available dose. For these patients, as well as patients who require additional therapy with low-dose acetylsalicylic acid (ASA) or other medicines likely to increase gastrointestinal risk, combination treatment with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered.

If your child has a history of gastro-intestinal side effects you should report any unusual abdominal symptoms (especially gastro-intestinal bleeding) particularly in the initial stages of treatment. Caution should be advised if your child is receiving at the same time medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulant medicines such as warfarin, selective serotonin-reuptake inhibitors, which are used amongst other things for the treatment of depressive mood, or anti-platelet medicines such as ASA (see Section 2: "Taking other medicines").

If your child experiences bleeding or ulcers in the stomach or intestines during treatment, stop administering Brupro for Children. Inform your doctor immediately if your child has any unusual abdominal symptoms.

NSAIDs should be used with caution in patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease), as their condition may get worse (see section 4).

#### Effects on the cardiovascular and cerebrovascular system

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.

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 attack “TIA”).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

#### Skin reactions

Serious skin reactions with reddening and blistering, some of them fatal, (exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis/Lyell's syndrome) have been reported very rarely in association with the use of NSAIDs (see Section 4).

Patients appear to be at highest risk of these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first month of treatment.

Brupro for Children should be discontinued and a doctor consulted at once at the first appearance of skin rash, mucous-membrane lesions, or any other signs of hypersensitivity.

During chicken pox (varicella) it is advisable to avoid the use of Brupro for Children.

#### Other information

Brupro for Children should only be used after careful consideration of the risk/benefit ratio in patients with:

- certain congenital disorders affecting blood formation (e.g. acute intermittent porphyria);
- certain autoimmune diseases (systemic lupus erythematosus and mixed connective tissue disease).

*Particularly careful medical surveillance is required:*

- in impaired kidney or liver function;
- in dehydration;
- immediately after major surgery;
- in an allergy (e.g. skin reactions to other medications, asthma, hay fever), chronic swelling of the nasal mucosa or COPD (chronic obstructive pulmonary disease).

Very rarely, severe acute hypersensitivity reactions (e.g. anaphylactic shock) have been observed. At the first signs of a severe hypersensitivity reaction after taking Brupro for Children treatment must be stopped. Depending on the symptoms, any medical treatment required must be started by specialists.

Ibuprofen can temporarily inhibit blood platelet function (blood platelet aggregation). Patients with blood clotting disorders should therefore be carefully monitored.

During prolonged use of Brupro for Children, regular monitoring of liver enzymes, kidney function and the blood count is required.

The doctor or dentist is to be asked or informed if Brupro for Children is administered before surgical procedures.

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.

In general, habitual intake of painkillers may lead to permanent kidney damage with a risk of kidney failure (analgesic nephropathy), especially when several pain-killing substances are combined.

NSAIDs such as ibuprofen may mask the symptoms of infection and fever.

Adequate hydration should be ensured, as dehydration can lead to renal insufficiency when ibuprofen is given.

### *Children*

Not intended for children below 5 kg body weight or below 3 months of age.

### **Other medicines and Brupro for Children**

Tell your doctor or pharmacist if your child is taking, has recently taken, or might take 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, beta-blockers such as atenolol medicines, 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.

The effects of the following drugs or drug groups can be affected when Brupro for Children is taken at the same time.

*Increase in the effect and/or side effects:*

- If the following medicines are taken at the same time, the blood concentrations of these medicines may increase:
  - Digoxin (medicine for strengthening the output of the heart)
  - Phenytoin (medicine for treating seizures)
  - Lithium (medicine for treating psychiatric disorders)

A check of serum-lithium levels, serum-digoxin and serum-phenytoin levels is not required as a rule if used correctly (over a maximum 3 days).

- Anti-clotting medicines such as warfarin;
- Methotrexate (medicine for treating cancer or certain rheumatic disorders): Do not take Brupro for Children within 24 hours before or after administration of methotrexate. This may lead to raised concentrations of methotrexate and to an increase in its side effects.
- Acetylsalicylic acid and other anti-inflammatory painkillers (non-steroidal anti-inflammatory drugs), as well as glucocorticoids (medicines containing cortisone or cortisone-like substances): An increased risk of ulcers and bleeding in the gastro-intestinal tract exists;
- Anti-platelet agents and selective serotonin-reuptake inhibitors (medicines for treating depressive mood): An increased risk of bleeding in the gastro-intestinal tract exists.
- Medicines that contain probenecid or sulfin pyrazone (for treating gout): These may delay the excretion of ibuprofen. There may be accumulation of ibuprofen in the body with an increase in its side effects through this.
- Herbal extracts: Ginkgo biloba may potentiate the risk of bleeding with NSAIDs.

#### *Weakening of the effect:*

- Medicines for increasing fluid excretion (diuretics) and medicines for too high blood pressure (antihypertensives) and there could be a possible increased risk for the kidneys.
- ACE inhibitors (medicines for treating heart failure and high blood pressure): Risk of a kidney-function disturbance occurring is increased.
- Acetylsalicylic acid in a low dose: The effect of low-dose acetylsalicylic acid on the coagulation-promoting blood platelets may be impaired.
- Mifepristone: A decrease in the efficacy of the medicinal product can theoretically occur due to the antiprostaglandin properties of NSAIDs. Limited evidence suggests that co-administration of NSAIDs on the day of prostaglandin administration does not adversely influence the effects of mifepristone or the prostaglandin on cervical ripening or uterine contractility and does not reduce the clinical efficacy of medicinal termination of pregnancy.

#### *Other possible interactions:*

- Zidovudine (medicine for treating HIV infection): An increased risk exists of bleeding of the joints and bruises in haemophiliacs with HIV infection.
- Cyclosporin (medicine for suppressing the immune response, after a transplant for example, and for treating rheumatism): The risk exists of your kidneys being damaged.
- Tacrolimus: The risk exists of your kidneys being damaged.
- Potassium-sparing water-removing\_agents\_(certain diuretics): If taken at the same time, there may be an increase in potassium levels.
- Sulphonylureas (medicines for lowering blood sugar): Although interactions between ibuprofen and sulphonylureas, unlike other NSAIDs, have not yet been described, your blood-sugar values should be checked as a precaution if taken at the same time.
- Quinolone antibiotics: There may be an increased risk of convulsions.
- Concomitant administration of ibuprofen with CYP2C9 inhibitors may increase the exposure to ibuprofen (CYP2C9 substrate). In a study with voriconazole and fluconazole (CYP2C9 inhibitors), an increased S(+)-ibuprofen exposure by approximately 80 to 100% has been shown. Reduction of the ibuprofen dose should be considered when potent CYP2C9 inhibitors are administered concomitantly, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole.
- Cholestyramine: At concomitant administration of ibuprofen and cholestyramine the absorption of ibuprofen is delayed and decreased. The medicines should be administered with a few hours interval.
- Baclofen (medicine for treating spasticity): Baclofen toxicity may develop after starting ibuprofen.
- Ritonavir (medicine for treating HIV infection): Ritonavir may increase the plasma concentrations of NSAIDs.
- Aminoglycosides (a certain group of antibiotics): NSAIDs may decrease the excretion of aminoglycosides.

#### **Brupro for Children with alcohol**

If possible, you should not drink alcohol during use of Brupro for Children, as side effects, particularly those that affect the gastro-intestinal tract or the central nervous system, may be increased.

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

##### *Pregnancy*

Tell your doctor if your child becomes pregnant during intake of Brupro for Children. Do not take this medicine in the last 3 months of pregnancy. Avoid the use of this medicine in the first 6 months of pregnancy unless your doctor advises otherwise.

#### Breast-feeding

Only small amounts of ibuprofen and its decomposition products pass into the breast milk. As no harmful effects to infants are known to date, it is not usually necessary to interrupt breast-feeding during short-term use of ibuprofen at the recommended doses.

#### Fertility

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

#### **Driving and using machines**

As central nervous side effects like tiredness and dizziness may occur if Brupro for Children is used at higher dosage, reactions may be changed and the ability to take part actively in road traffic and to operate machines may be impaired in isolated cases. This applies to an increased extent in combination with alcohol. You are then no longer able to react fast and purposely enough to unexpected and sudden events. Do not drive cars or other vehicles in this case! Do not operate tools or machines! Do not work without a secure foothold!

#### **Brupro for Children contains maltitol liquid and sodium**

If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicinal product contains 2.34 mmol (or 53.85 mg) sodium per highest single dose of 15ml. To be taken into consideration by patients on a controlled sodium diet.

### **3 How to take Brupro for Children**

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

The recommended dose is:

<b>Body weight (Child's age)</b>	<b>Quantity ibuprofen (method of administration)</b>	<b>Frequency in 24 hours (max. daily ibuprofen dose)</b>
5-6kg (3-8 months)	1 x 2.5ml	3 times (150mg)
7-9kg (9-11 months)	1 x 2.5ml	3 to 4 times (150-200mg)
10-15kg (1-3 years)	1 x 5ml	3 times (300mg)
16-19kg (4-5 years)	1 x 7.5ml (5ml+2.5ml)	3 times (450mg)
20-29kg (6-9 years)	1 x 10ml (2x5ml)	3 times (600mg)

30-39kg (10 -11 years)	1 x 15ml (3x5ml)	3 times (900mg)
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In children Brupro for Children is dosed according to body weight (BW), generally 7 to 10 mg/kg BW as a single dose, up to a maximum of 30 mg/kg BW as a total daily dose.

After taking a single dose, wait for at least 6 hours before taking the next one. Do not exceed the recommended dose or length of treatment (maximum 3 days).

Brupro for Children is not intended for use in children under 5 kg body weight or under 3 months of age.

For oral use.

Shake the bottle vigorously before use. The package includes a 5 ml oral syringe (graduated in 0.25 ml steps up to 5 ml). 5 ml oral suspension corresponds to 100 mg ibuprofen.

The oral suspension can be taken without regard to meals. People with a sensitive stomach are recommended to take Brupro for Children during meals.

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.

For short-term use only.

If symptoms worsen or persist for more than 3 days, medical advice should be sought.

In children and adolescents Brupro for Children is dosed according to body weight (BW), generally 7 to 10 mg/kg BW as a single dose, up to a maximum of 30 mg/kg BW as a total daily dose.

Please talk to your doctor or pharmacist if you feel that the effect of Brupro for Children is too strong or too weak.

### **If your child takes more Brupro for Children than they should**

Possible symptoms of an overdose are:

- Central nervous disturbances like headache, dizziness, light-headedness and unconsciousness (also seizures in children)
- Gastro-intestinal disturbances like stomach ache, nausea and vomiting, bleeding in the gastro-intestinal tract
- Function disturbances of the liver and kidneys
- Drop in blood pressure
- Lessened breathing (respiratory depression)
- Blue-red coloration of skin and mucous membranes (cyanosis)

There is no specific antidote.

If an overdose with Brupro for Children is suspected, notify a doctor at once. According to the severity of the poisoning, they can decide about the measures that might be required.

## **If your child forgets to take Brupro for Children**

Do not take 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 this medicine and seek immediate medical help if your child develops:**

- **signs of intestinal bleeding** such as: relatively severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- **signs of rare but serious allergic reaction** 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 skin.

The listing of undesirable effects below comprises all side effects reported during treatment with ibuprofen, including those reported during high-dose long-term therapy in patients with rheumatic disorders. Reported frequencies other than very rare reports refer to short-term use of daily doses of up to 1200mg ibuprofen (= 60 ml Brupro for Children) for oral formulations and a maximum of 1800 mg for suppositories.

It must be accounted for that the following adverse drug reactions are predominantly dose-dependant and vary from patient to patient.

The most commonly observed side effects are gastro-intestinal in nature.

Stomach/duodenal ulcers (peptic ulcers), perforation or gastro-intestinal bleeding, sometimes fatal, particularly in the elderly, may occur (see Section 2). Nausea, vomiting, diarrhoea, flatulence, constipation, digestive complaints, abdominal pain, tarry stool, vomiting blood, ulcerative stomatitis (inflammation of the mucous membrane of the mouth with ulceration), worsening of the intestinal disorders ulcerative colitis and Crohn's disease (see Section 2) have been reported following use.

Less frequently, inflammation of the mucous membrane of the stomach (gastritis) has been observed. The risk of gastro-intestinal bleeding in particular occurring depends on the dose range and the length of use.

Oedema, high blood pressure and heart failure have been reported in association with NSAID treatment.

Medicines such as Brupro for Children may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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

Stomach and digestive system: Gastro-intestinal complaints like heartburn, stomach ache, nausea, vomiting, flatulence, diarrhoea, constipation and slight gastro-intestinal blood losses that may cause a lack of red blood cells (anaemia) in exceptional cases

### **Uncommon side effects (may affect up to 1 in 100 people)**

**Immune system:** Hypersensitivity reactions with skin rashes and skin itching, as well as asthma attacks (possibly with drop in blood pressure). A doctor is to be informed at once in this case, and Brupro for Children must no longer be taken.

**Nervous system:** Central nervous disturbances like headache, dizziness, sleeplessness, agitation, irritability or tiredness.

**Eyes:** Visual disturbances

A doctor is to be informed at once in this case, and Brupro for Children must no longer be taken.

**Stomach and digestive system:** Stomach/duodenal ulcers (peptic ulcers), potentially with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), increase of ulcerative colitis or Crohn's disease, inflammation of the lining of the stomach (gastritis).

**Skin and hair:** Various skin rashes.

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

**Ears:** Ear noises (tinnitus).

**Kidneys and urinary system:** Kidney-tissue damage (papillary necrosis), particularly in long-term therapy, and raised uric acid concentrations in the blood may also occur.

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

**Infections and infestations:** A worsening of infection-related inflammations (e.g. development of necrotising fasciitis) coinciding with the use of certain anti-inflammatory medicines (non-steroidal anti-inflammatory drugs, to which Brupro for Children also belongs) has been described.

Symptoms of an inflammation of the brain lining (aseptic meningitis), like severe headache, nausea, vomiting, fever, neck stiffness or consciousness clouding have been observed.

An increased risk appears to exist for patients who are already suffering from certain auto-immune disorders (systemic lupus erythematosus, mixed connective-tissue disease).

If signs of an infection (e.g. reddening, swelling, overheating, pain, fever) occur or get worse during use of Brupro for Children, ask a doctor for advice without delay.

**Blood and lymph system:** Disturbances to blood formation (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis.)

The first signs may be fever, sore throat, superficial wounds in the mouth, influenza-like complaints, severe fatigue, nosebleeds and skin bleeding.

In these cases, stop taking the medicine immediately and go to a doctor. Do NOT attempt any kind of self-treatment with pain- or fever-lowering medicines.

**Immune system:** Severe general allergic reactions

They may emerge as water accumulation in the face (oedema), swelling of the tongue, internal swelling of the larynx with narrowing of the airways, breathlessness, racing heart, drop in blood pressure up to life-threatening shock.

If one of these symptoms occurs, which can happen even on first use, the immediate assistance of a doctor is required.

**Psychiatric disorders:** Psychotic reactions, depression.

Heart and vessels: Pounding heart (palpitations), heart failure, heart attack ("myocardial infarction"), high blood pressure (arterial hypertension).

Respiratory, thoracic and mediastinal disorders: asthma, bronchospasm, dyspnoea and wheezing.

Stomach and digestive system: Inflammation of the gullet (oesophagitis) and of the pancreas (pancreatitis), formation of membrane-like narrowing in the small and large intestines (intestinal, diaphragm-like strictures).

Liver and gall bladder:

Liver-function disturbances, liver damage, particularly in long-term therapy, liver failure, acute inflammation of the liver (hepatitis.) On prolonged administration, the liver values should be checked regularly.

Skin and hair:

Severe skin reactions like skin rash with reddening and blistering (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia.)

In exceptional cases, severe skin infections and soft-tissue complications may occur during a chickenpox (varicella) infection (see also "Infections and infestations").

Kidneys and urinary system: Lessening of urine excretion and increased water retention in the tissue (oedemas), particularly in patients with high blood pressure or impaired kidney function, nephrotic syndrome (water accumulation in the body [oedemas] and pronounced protein excretion in the urine), inflammatory kidney disorder (interstitial nephritis), which may be accompanied by acute kidney-function disturbance.

Lessening of urine excretion, accumulation of water in the body (oedemas), as well as generally feeling unwell, may be a sign of a kidney disorder up to kidney failure. If the stated symptoms occur or get worse, then you must stop taking Brupro for Children and go to a doctor immediately.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2: Tel : +353 1 6764971; Fax : + 353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail : [medsafety@hpra.ie](mailto:medsafety@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 after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Once opened, this medicine is stable at temperature below 25°C for 6 months.

Do not use this medicine if you notice the visible signs of deterioration.

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 5ml oral suspension contains 100 mg ibuprofen.

The package includes a 5 ml oral syringe (graduated in 0.25 ml steps up to 5 ml).

The other ingredients are:

Sodium benzoate (E211), citric acid anhydrous, sodium citrate, saccharin sodium, sodium chloride, hypromellose, xanthan gum, maltitol liquid, glycerol (E422), strawberry flavor (flavourings identical to natural substances, flavouring preparations, maltodextrin (maize based), E 1505 triethyl citrate, E 1520 propylene glycol, added benzyl alcohol), purified water.

### **What Brupro for Children looks like and contents of the pack**

Off-white oral suspension.

Brupro for Children is available in bottles with a child-resistant closure of 100ml, 150ml and 200ml oral suspension.

The package includes a 5 ml oral syringe (graduated in 0.25 ml steps up to 5 ml).

Not all pack-sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturers:**

#### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

#### **Manufacturers**

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany

S.C. Sandoz, S.R.L., Str. Livezeni nr. 7A, RO-540472 Targu-Mures, Romania

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