FENPAED IBUPROFEN 100 MG/5 ML ORAL SUSPENSION

PL 04917/0082

UKPAR

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Pinewood Laboratories Limited a Marketing Authorisations (licence) for the medicinal product Fenpaed Ibuprofen 100 mg/5 ml Oral Suspension (Product Licence number: 04917/0082). This product is available from pharmacies without a prescription.

This product contains the active ingredient ibuprofen. Ibuprofen is a painkiller for the relief of mild to moderate muscular pain, headache, earache, sore throat, dental pain and backache. It can also be used in minor injuries such as sprains and strains and it reduces temperature in post-immunisation fever, cold and influenza.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Fenpaed Ibuprofen 100 mg/5 ml Oral Suspension outweigh the risks, hence a Marketing Authorisation has been granted.

FENPAED IBUPROFEN 100 MG/5 ML ORAL SUSPENSION

PL 04917/0082

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Fenpaed Ibuprofen 100 mg/5 ml Oral Suspension (PL 04917/0082) to Pinewood Laboratories Limited on 12 November 2007. This medicinal product is available at pharmacies only.

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC, as amended, for Fenpaed Ibuprofen Oral Suspension 100mg/5ml. The reference product is Fenpaed 100 mg/5 ml Oral Suspension (also called Calprofen or Enterprise Ibuprofen 100 mg/5 ml Oral Suspension; PL 04917/0044), held by Pinewood Laboratories Limited.

No new data were submitted, nor was it necessary for this simple application as the data are identical to those of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) was generated for it.

PHARMACEUTICAL ASSESSMENT REPORT

INTRODUCTION

The licence for the reference product is held by Pinewood Laboratories Limited, i.e. this applicant, hence permission to cross-refer is given. Fenpaed Ibuprofen 100 mg/5 ml Oral Suspension is identical to the reference product.

ACTIVE SUBSTANCE

Two manufacturers are responsible for the manufacture of the ibuprofen.

Both of these suppliers have been issued a Certificate of Suitability for the drug substance. This means that the ibuprofen used in this product complies with the monographs of the European Pharmacopoeia and Directives 2001/83/EC and 2001/82/EC.

FINISHED PRODUCT

The manufacturer of the finished product possesses a valid manufacturing licence.

The finished product specification and manufacturing process are identical to those of the reference product, and are, therefore, satisfactory.

There are no excipients from sources of animal or human origin.

EXPERT REPORTS

Satisfactory expert reports and curriculum vitae of the experts are provided.

PRODUCT LITERATURE

Summary of Product Characteristics (SPC)

This is identical to the reference product.

Labelling

This is satisfactory.

PIL

This is satisfactory.

Marketing Authorisation Form (MAA Form)

This is satisfactory.

RECOMMENDATION

A licence can be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for applications of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with these applications and none are required for applications of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The product is identical to the already-granted reference product. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY AND SAFETY

The efficacy of ibuprofen has been well documented in the past. No new or unexpected safety concerns arise from this application.

The SPCs, PILs and labelling are satisfactory.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The product is identical to the cross-reference product. The risk benefit ratio is considered to be positive.

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation applications on 29 August 2007
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 23 October 2007
3	The application was determined on 12 November 2007

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fenpaed Ibuprofen 100 mg/5 ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 100 mg / 5ml
For excipients - see section 6.1

3 PHARMACEUTICAL FORM

Oral Suspension
Sugar Free, Colour Free and Strawberry Flavour

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prescription and OTC: Ibuprofen 100 mg / 5 ml Oral Suspension is used as an analgesic for relief of mild to moderate muscular pain, post-immunisation pyrexia, symptomatic relief of headache, earache, dental pain and backache. It can also be used in minor injuries such as sprains and strains. Ibuprofen 100 mg / 5 ml Oral Suspension is effective in the relief of feverishness and symptoms of colds and influenza.

Prescription Only: Ibuprofen 100 mg / 5 ml Oral Suspension is indicated for its analgesic and anti-inflammatory effects in the treatment of dysmenorrhoea, neuralgia, post–operative pain, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies.

In the treatment of non-articular rheumatic conditions, Ibuprofen 100 mg / 5 ml Oral Suspension is indicated for periarticular conditions such as frozen shoulder (capsulitis), bursitis, tendonitis, tenosynovitis and low back pain. Ibuprofen 100 mg / 5 ml Oral Suspension can also be used in soft tissue injuries such as sprains and strains.

4.2 Posology and method of administration

For oral administration and short-term use only.

Adults: The recommended dosage of Ibuprofen 100 mg / 5 ml Oral Suspension is 1200-1800 mg daily in divided doses. Some patients can be maintained on 600-1200 mg daily. In severe or acute conditions, it can be advantageous to increase the dosage until the acute phase is brought under control, provided the total daily dose does not exceed 2400mg in divided doses.

Children:

For pain and fever - 20mg/kg/day in divided doses (including OTC use).

Infants 3-6 months
weighing more than 5 kg: One 2.5 ml dose may be taken 3 times in 24 hours
Infants 6-12 months: 2.5ml three times a day.
Children 1-2 years: 2.5ml three to four times a day

Children 3-7 years: 5ml three to four times a day
Children 8-12 years: 10ml three to four times a day.

Post-immunisation fever: 2.5ml (50mg) followed by one further dose of 2.5ml (50mg) six hours later if necessary. No more than 2 doses in 24 hours. If fever is not reduced, consult a doctor.

For Juvenile Rheumatoid Arthritis (prescription only use): Doses up to 30-40mg/kg/day may be taken in three or four divided doses.

Elderly: No special dosage modifications are required unless renal or hepatic function is impaired, in which case dosage should be assessed individually.

Do not give to children under 3 months of age.

If the child's (aged over 6 months) symptoms persist for more than 3 days, consult your doctor promptly. For children under 6 months medical advice should be sought promptly after 24 hours use (3 doses) if the symptoms persist.

4.3 Contraindications

Hypersensitivity to ibuprofen or any of the constituents in the product.

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs.

Active or previous peptic ulcer.

History of upper gastrointestinal bleeding or perforation, related to previous NSAID's therapy.

Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors (see section 4.5 Interactions).

Severe hepatic failure, renal failure or heart failure (see section 4.4, Special warnings and precautions for use).

Last trimester of pregnancy (see section 4.6 Pregnancy and lactation).

Severe heart failure.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.4 Special warnings and precautions for use

The elderly are at increased risk of the serious consequences of adverse reactions.

Systemic lupus erythematosus and mixed connective tissue disease – increased risk of aseptic meningitis (see section 4.8 Undesirable effects).

Chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease) – as these conditions may be exacerbated (see section 4.8 Undesirable effects).

Undesirable effects may be minimised by using the minimum effective dose for the shortest possible duration.

There is limited evidence that drugs which inhibit cyclo-oxygenase/prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment.

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events.

Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.

Caution should be advised in patients receiving concomitant medications which could increase the risk of gastrotoxicity or bleeding, such as corticosteroids, or anticoagulants such as warfarin or anti-platelet agents such as aspirin (see section 4.5).

When GI bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn.

Administration of NSAID'S such as Ibuprofen may cause dose dependent renal toxicity in patients with reduced renal blood flow or blood volume where renal prostaglandins support the maintenance of renal perfusion. Patients at risk of this reaction include those with impaired renal function, heart failure or liver dysfunction. This is of particular importance in hypertension and/or cardiac impairment as renal function may deteriorate and/or fluid retention occur. Caution is therefore required in the use of Ibuprofen in such patients.

Ibuprofen should be used with caution in patients with bronchial asthma or allergic disease, since such patients may have NSAID – sensitive asthma which has been associated with severe bronchospasm.

Not recommended for children under 3 months.

Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200mg daily) is associated with an increased risk of myocardial infarction.

The label will include:

Read the enclosed leaflet before taking this product.

Do not give this product if your baby or child

- Has or has ever had a stomach ulcer, perforation or bleeding
- Is allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers
- Is taking other NSAIDs painkillers, or aspirin with a daily dose above 75 mg

Speak to a pharmacist or your doctor before giving this product if your baby or child

- Has asthma, liver, heart, kidney or bowel problems

If you are an adult taking this product you should not take Ibuprofen 100mg/5ml Oral Suspension in the last 3 months of pregnancy and you should contact your doctor or pharmacist before taking it in the first 6 months of pregnancy or if trying to get pregnant.

Additional Warnings for OTC use

Do not give to babies aged 3-6 months for more than 24 hours.

Do not give to children aged 6 months and older for more than 3 days.

Consult your doctor promptly if symptoms persist or worsen.

Do not exceed the stated dose.

Not recommended for children under 3 months.

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should not be used in combination with:

Aspirin: Unless low-dose aspirin (not above 75 mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions (see section 4.3 Contraindications).

Other NSAIDs: As these may increase the risk of adverse effects (see section 4.3 Contraindications).

Ibuprofen should be used with caution in combination with:

Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin (see section 4.4).

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs.

Corticosteroids: May increase the risk of adverse reactions in the gastrointestinal tract (see section 4.4 Special warnings).

Lithium: There is evidence for potential increase in plasma levels of lithium.

Methotrexate: There is potential of an increase in plasma methotrexate.

Zidovudine: There is evidence of an increased risk of haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

4.6 Pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal experiments the use of Ibuprofen 100mg/5ml Oral Suspension, should, if possible, be avoided during the first 6 months of pregnancy.

During the 3rd trimester, ibuprofen is contraindicated as there is a risk of premature closure of the foetal ductus arteriosis with possible persistent pulmonary hypertension. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child (see section 4.3 Contraindications)

In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect breast-fed infants adversely.

See section 4.4 regarding female fertility.

4.7 Effects on ability to drive and use machines

None expected at recommended doses and duration of therapy.

4.8 Undesirable effects

Hypersensitivity reactions have been reported and these may consist of:

(a) Non-specific allergic reactions and anaphylaxis
(b) Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm, dyspnoea.
(c) Various skin reactions, e.g. pruritis, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

The following list of adverse effects relates to those experienced with ibuprofen at OTC doses, for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Hypersensitivity reactions:
Uncommon: Hypersensitivity reactions with urticaria and pruritis.

Very rare: Severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock).

Exacerbation of asthma and bronchospasm.

Gastrointestinal:
Uncommon: Abdominal pain, nausea and dyspepsia.
Rare: Diarrhoea, flatulence, constipation and vomiting.
Very rare: Peptic ulcer, perforation or gastrointestinal haemorrhage, sometimes fatal, particularly in the elderly. Exacerbation of ulcerative colitis and Crohn's disease (see section 4.4)

Nervous System:
Uncommon: Headache

Renal:

Very rare: Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema.

Hepatic:
Very rare: Liver disorders.

Haematological:
Very rare: Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, panytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

Skin:
Uncommon: Various skin rashes

Very rare: Severe forms of skin reactions such as erythema multiforme and epidermal necrolysis can occur.

Immune System:
In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed (see section 4.4).

Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment.

Clinical trial and epidemiological data suggest that use of ibuprofen (particularly at high doses 2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

4.9 Overdose

In children ingestion of more than 400 mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5 – 3 hours.

Symptoms
Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and 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.

Management
Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ibuprofen is a Phenylpropionic Acid derivative, which has analgesic anti-inflammatory and antipyretic actions. These actions are thought to be from its inhibitory effect on the enzyme cyclo-oxygenase which results in a reduction in prostaglandin synthesis.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. Peak plasma concentrations occur about 1 to 2 hours after ingestion with food or in 45 minutes if taken on an empty stomach. These times may vary with different dosage forms.

The excretion is rapid and complete via the kidneys.

The half-life of ibuprofen is about 2 hours.

In limited studies, ibuprofen appears in the breast milk in very low concentrations.

It is metabolised to two inactive metabolites and these are rapidly excreted in urine. About 1 percent is excreted in urine as unchanged Ibuprofen and about 14 percent as conjugated Ibuprofen

Ibuprofen is extensively bound to plasma proteins.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E422), xanthan gum, maltitol syrup (Lycasin 80/55 (E965)), polysorbate 80, saccharin sodium (E954), citric acid monohydrate, sodium methylhydroxybenzoate, sodium propylhydroxybenzoate, purified water and strawberry flavour.

6.2 Incompatibilities

None stated except as in ‘Interactions with other medicaments’.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25ºC.
Keep out of reach and sight of children

6.5 Nature and contents of container

An amber glass bottle sealed with child resistant, tamper evident cap.
Pack sizes available: 100ml, 150ml, 200ml and 500ml

6.6 Special precautions for disposal and handling

Shake well before use. Return any left over medicine to the Pharmacist.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Limited
Ballymacarbry,
Clonmel,
Co. Tipperary,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

PL 04917/0082

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/11/2007

10 DATE OF REVISION OF THE TEXT

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET
FENPAED
100 mg/5 ml Oral Suspension
Ibuprofen

Please read this leaflet carefully before giving this medicine.
If you have any further questions or are not sure about anything, ask your pharmacist.

What you should know about Fenpaed?
The name of your medicine is Fenpaed 100 mg/5 ml Oral Suspension. Each 5 ml of oral suspension contains 100 mg of the active Ibuprofen. It also contains 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.
Each bottle contains 100 ml / 150 ml / 200 ml / 500 ml of oral suspension.
Ibuprofen belongs to a group of medicines called anti-inflammatory pain killers.

Product Licence Holder and Manufacturer:
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

What is Fenpaed for?
Fenpaed is used as a painkiller for relief of mild to moderate muscular pain, headache, earache, sore throat, dental pain and backache. Fenpaed can also be used in minor injuries such as sprains and strains. Fenpaed reduces temperature in post-immunisation fever, colds and influenza.

Before you give Fenpaed:
DO NOT give Fenpaed to your child:
1. If your child has or has ever had a stomach ulcer or other gastric complaint
2. If your child suffers from asthma or if they have had an allergic reaction or wheezing after taking Ibuprofen, aspirin or other anti-inflammatory painkillers
3. If your child is sensitive to any of the ingredients of Fenpaed
4. If your child is taking any other anti-inflammatory pain killers (NSAIDs)
5. If your child has or has previously had kidney, heart or severe liver problems

Before you give Fenpaed tell your doctor:
1. If your child suffers from high blood pressure
2. If your child suffers from lupus or a mixed connective tissue disease
3. If your child suffers from a chronic inflammatory intestinal disease such as ulcerative colitis or Crohn's disease
4. If your child is taking any of the following medicines:
   - Diuretics (water tablets)
   - Tablets for high blood pressure
   - Medicines such as warfarin, to prevent blood clots
   - Aspirin, lithium, methotrexate, zidovudine or corticosteroids
   - Any other Ibuprofen preparations, including those you can buy without prescription.

This product is intended for use in children. If an adult is taking this product all of the above statements apply, however, there are the following additional warnings.

Do not take if you are taking aspirin at doses above 75mg daily. If you are on low dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take Fenpaed.

Medicines such as Ibuprofen 100 mg/5 ml Oral Suspension 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.

If you or your child have heart problems, previous stroke or if you think that you or your child might be at risk of these conditions (for example if you or your child have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss the treatment with your doctor or pharmacist.

Ibuprofen should NOT be taken during the last 3 months of pregnancy, as it may be harmful to the unborn child. Pregnant women intending to use this product should seek medical advice before use as it should only be taken on doctor's advice during the first 6 months of pregnancy. Fenpaed belongs to a group of medicines which may impair fertility in women. The effect is reversible on stopping the medicine. If you are having problems becoming pregnant talk to your doctor before using this product.

This product contains maltitol. If you have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before taking/giving this medicinal product. Maltitol may have a mild laxative effect. Calorific value 2.3 kcal/g maltitol.

This product contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).

3LF

How should Fenpaed be given?
Shake the bottle well before measuring the dose. A measuring spoon is provided to ensure accuracy.

Children
Fenpaed should NOT be given if your child weighs less than 5kg. The usual daily dose in children is 20mg per kg of bodyweight in divided doses which can be given as follows:

DOSAGE: Children (A spoon is provided to measure doses of 2.5 ml or 5 ml)	
3-6 months (weighing over 5kg)	2.5 ml 3 times a day (Do not give for more than 24 hours)
6 months - 1 year	2.5 ml 3 times a day
1 year - 2 years	2.5 ml 3 to 4 times a day
3 years - 7 years	5 ml 3 to 4 times a day
8 years - 12 years	10 ml 3 to 4 times a day
Do not give to babies under 3 months	

Post-immunisation fever: One small spoonful (2.5ml), followed by another small spoonful (2.5ml) six hours later if necessary. Not more than 2 doses should be given in 24 hours. If fever is not reduced, consult a doctor.

WARNING: DO NOT EXCEED THE STATED DOSE

For short term use only. Do not give to babies aged 3-6 months for more than 24 hours. Do not give to children aged 6 months and older for more than 3 days. Consult your doctor promptly if symptoms persist or worsen.

What to do if you miss a dose, or give too much Fenpaed?
If you forget to give a dose, give it as soon as you remember, unless it is almost time for the next dose. Never double-up on a dose to make up for the missed dose. If your child or someone you know accidentally takes a lot more than the stated dose (an overdose), you should contact a doctor immediately, or go to the nearest hospital casualty department.

Will Fenpaed cause any problems?
Like all medicines Fenpaed can have some side-effects although these are rare and usually mild. The most common side-effect is irritation of the stomach which can cause problems in some patients.
If your child suffers from the following stop giving the medicine and seek immediate medical help:
- Pass blood in their faeces (stools/motions)
- Pass black tarry stools
- Vomit blood or dark particles that look like ground coffee

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, itching or bruising, lightheadedness or racing heart
- Yellowing of the eyes and/or skin
- Severe sore throat with high fever
- Blurred or disturbed vision
- Hallucination
- Fluid retention, e.g. swollen ankles, not passing enough urine.

Other unusual effects may include headache and occasionally hypersensitivity reactions may occur which can cause skin rashes. Rarely Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated. Very rarely, blood disorders and liver and kidney problems may occur with Ibuprofen. If any of these become troublesome or last more than a few days, tell your doctor. If your child experiences any other unusual symptoms while taking this medicine, tell your doctor or pharmacist.

Medicines such as Ibuprofen 100 mg/5 ml Oral Suspension may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

Storing your medicine
Do not take your medicine after the expiry date shown on the bottle.
Do not store above 25°C. Keep all medicines out of reach and sight of children.

Other Information
Remember: This medicine is for you or your child. Never give it to anyone else, even if their symptoms are the same as yours. This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who has access to additional information.

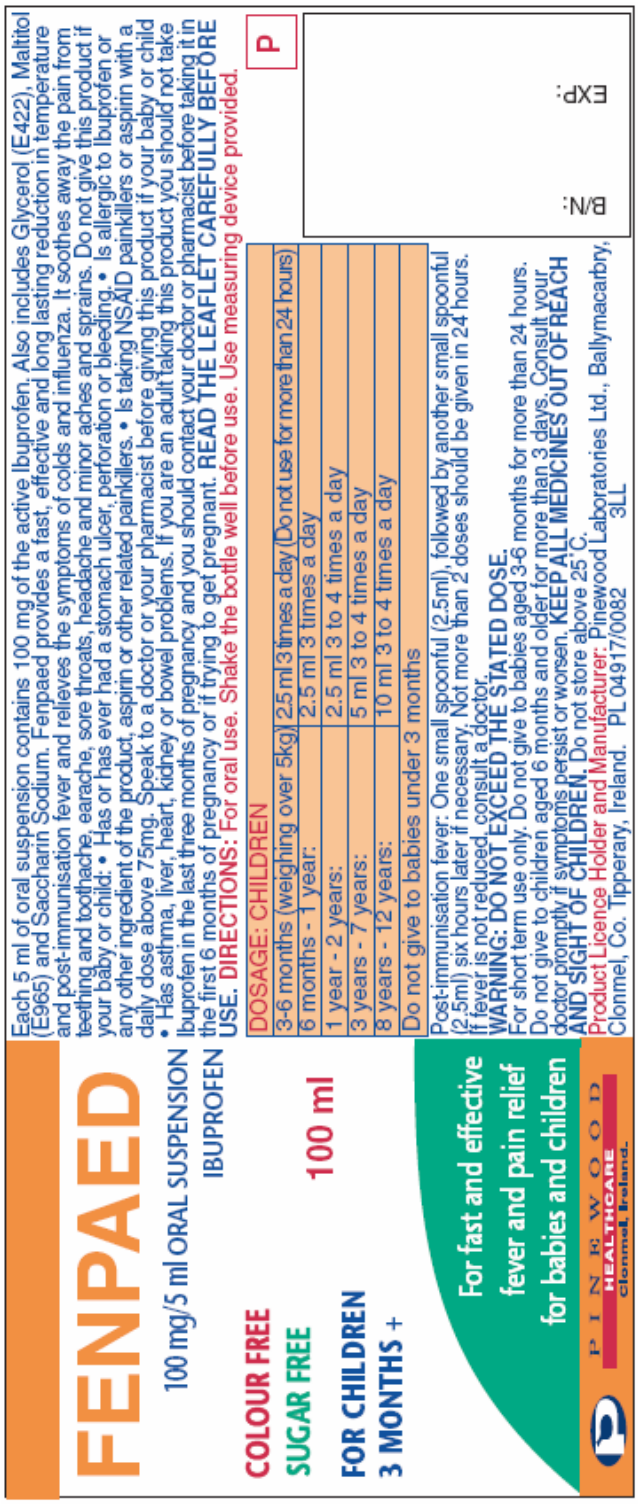
Leaflet prepared:
PL Number: 04917/0082

PINEWOOD HEALTHCARE
Clonmel, Ireland.

3LF

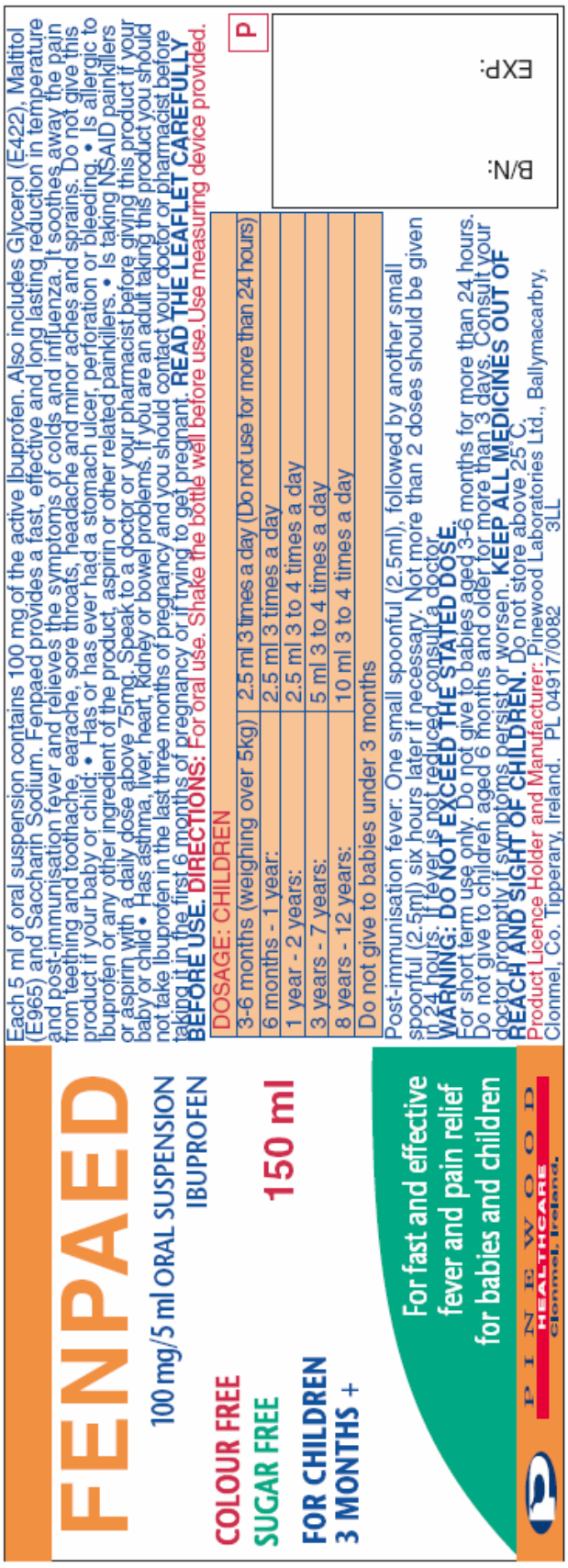
LABELLING

100 ml label:



100 ml carton:

150 ml label:


FENPAED
100 mg/5 ml ORAL SUSPENSION
IBUPROFEN
COLOUR FREE
SUGAR FREE
150 ml
FOR CHILDREN
3 MONTHS +
For fast and effective fever and pain relief for babies and children
PINEWOOD
HEALTHCARE
Clonmel, Ireland.
Each 5 ml of oral suspension contains 100 mg of the active Ibuprofen. Also includes Glycerol (E422), Maltitol (E965) and Saccharin Sodium. Fenpaed provides a fast, effective and long lasting reduction in temperature and post-immunisation fever and relieves the symptoms of colds and influenza. It soothes away the pain from teething and toothache, earache, sore throats, headache and minor aches and sprains. Do not give this product if your baby or child: • Has or has ever had a stomach ulcer, perforation or bleeding. • Is allergic to Ibuprofen or any other ingredient of the product, aspirin or other related painkillers. • Is taking NSAID painkillers or aspirin with a daily dose above 75mg. Speak to a doctor or your pharmacist before giving this product if your baby or child • Has asthma, liver, heart, kidney or bowel problems. If you are an adult taking this product you should not take Ibuprofen in the last three months of pregnancy and you should contact your doctor or pharmacist before taking it in the first 6 months of pregnancy or if trying to get pregnant. READ THE LEAFLET CAREFULLY BEFORE USE. DIRECTIONS: For oral use. Shake the bottle well before use. Use measuring device provided.
DOSAGE: CHILDREN
3-6 months (weighing over 5kg) 2.5 ml 3 times a day (Do not use for more than 24 hours)
6 months - 1 year: 2.5 ml 3 times a day
1 year - 2 years: 2.5 ml 3 to 4 times a day
3 years - 7 years: 5 ml 3 to 4 times a day
8 years - 12 years: 10 ml 3 to 4 times a day
Do not give to babies under 3 months
Post-immunisation fever: One small spoonful (2.5ml), followed by another small spoonful (2.5ml) six hours later if necessary. Not more than 2 doses should be given in 24 hours. If fever is not reduced, consult a doctor.
WARNING: DO NOT EXCEED THE STATED DOSE.
For short term use only. Do not give to babies aged 3-6 months for more than 24 hours. Do not give to children aged 6 months and older for more than 3 days. Consult your doctor promptly if symptoms persist or worsen. KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN. Do not store above 25°C.
Product Licence Holder and Manufacturer: Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 04917/0082
3LL
P
B/N:
EXP:

150 ml carton: