PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

PROPRIETARY NAME (and dosage form):

INFLAMAX PAEDIATRIC SUSPENSION

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to give it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- The leaflet is written in terms of giving this medicine to your child, but if you are an adult who is intending to take this medicine yourself the information in this leaflet will apply to you as well

What is in this leaflet

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

- **What Inflamax is and what it is used for**

This medicine contains Ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Inflamax Paediatric Suspension is indicated for the management of mild to moderate pain and inflammation. Inflamax Paediatric Suspension is also used to reduce fever.

Inflamax Paediatric Suspension is used in the management of mild to moderate pain and inflammation

in dysmenorrhoea, migraine, post-operative pain, dental pain, musculoskeletal and joint disorders

such as ankylosing spondylitis, osteoarthritis and rheumatoid arthritis including juvenile rheumatoid

arthritis, peri-articular disorders such as bursitis, and tensosynovitis, and soft tissue disorder such as pains and sprains.

- **What you need to know before you take Inflamax Paediatric Suspension**

Inflamax Paediatric Suspension is not recommended for children under 1 year of age or in those

weighing less than 7 kg.However, some children should not be given this medicine or you should seek the advice of their pharmacist or doctor first.

Do not give:

- **If your child is under 1 year old,** or weighs less than 7 kg

- **If your child has a stomach ulcer, perforation or bleeding,** or has had one twice or more in the past
- **If your child has had perforation or a bleeding stomach** after taking a non-steroidal anti-inflammatory medicine (your child may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in their stools or passed black tarry stools)
- **If your child is allergic** to ibuprofen or any other ingredients in the product, aspirin or other non-steroidal anti-inflammatory medicines (your child has ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- **If your child has severe heart, kidney or liver failure**
- **If your child is taking aspirin,** or other non-steroidal anti-inflammatory medicines

Other important information

Risk of heart attack or stroke: 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.

Inflamax Paediatric Suspension should be used with caution in the elderly.

Care is required in those receiving oral anti-coagulants, lithium, methotrexate and cardiac glycosides.

Patients with collagen disease may be at increased risk of developing aseptic meningitis.

Inflamax Paediatric Suspension should be discontinued in patients who experience blurred or

diminished vision, or changes in colour vision.

Inflamax paediatric suspension contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Inflamax paediatric suspension contains sucrose and sorbitol. This should also be taken into account in patients with diabetes mellitus. May be harmful to the teeth

Talk to your pharmacist or doctor:

- If your child has asthma, a history of asthma or other allergic disease
- If your child has other kidney, heart or liver problems (see above)
- If your child has heart problems including heart failure, angina (chest pain), or has 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” - see ‘**Risk of heart attack or stroke**’ under “Other important information”
- If your child has high blood pressure, diabetes, high cholesterol, has a family history of heart disease or stroke

If your child takes other medicines

Before you give this medicine, make sure that you tell your doctor or pharmacist about ANY other medicines you might be giving to the child at the same time. Ibuprofen may affect or be affected by some other medicines. For example:

- Other pain killers (including NSAIDs) and Aspirin
- Medicines to thin the blood (e.g. warfarin, ticlopidine)
- Medicines to treat high blood pressure (e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan), medicines for heart problems
- Corticosteroids (for pain and swelling)
- Lithium (for bipolar disorder)
- Methotrexate (for cancer, psoriasis or rheumatism)

Some other medicines may also affect or be affected by the treatment of Ibuprofen. You should therefore always seek advice of your doctor or pharmacist before you can use this medicine with any other medicines, including herbal and homeopathic remedies.

Other information

Information about some of the ingredients: Methyl Hydroxybenzoate O,1 % m/v, Propyl Hydroxybenzoate 0,05 % m/v, Sodium Benzoate 0,25 % m/v.

Information for adults intending to take this medicine

All the information in this leaflet applies to you as well.

If you are elderly you may be more likely to have some of the possible side effects listed later in the leaflet.

Pregnancy: Do not take this medicine if you are in the last 3 months of pregnancy. Talk to your pharmacist or doctor if you are in the first 6 months of pregnancy.

Breastfeeding: Talk to your pharmacist or doctor before you take this medicine.

If you are a woman of childbearing age taking this medicine, it may reduce your ability to become pregnant. This effect will be reversed on stopping the medicine.

- **How to give Inflamax Paediatric Suspention**

Shake the container before use.

Children:

Juvenile Rheumatoid Arthritis - 20 mg/kg of body mass daily in divided doses with up to 40 mg/kg being given daily if necessary.

Inflamax Paediatric Suspension is not recommended for children under 1 year of age or in those weighing less than 7 kg.

Pain: 5 mg/kg of body mass. A second dose of 5 mg/kg may be given after 2 hours if pain is not controlled, thereafter 5 mg/kg every 4-6 hours. If pain persists for more than 7 days, consult your physician.

Fever: 5 mg/kg of body mass every 4-6 hours. If fever persists more than three days consult your doctor.

Age	Daily Dosage	Body Mass
1 - 2 years	2,5ml 3 – 4 times daily	7 - 12 kg
3 - 7 years	2,5-5ml 3 – 4 times daily	14 - 23 kg

8 - 12 years	10 ml 3 - 4 times daily	25 - 40 kg

Give the lowest amount for the shortest possible time to relieve the symptoms.

If you give more than you should: If you have given more than you should, or if children have taken the medicine by accident always contact a doctor or nearest hospital to get an opinion on the risk and advice on action to be taken.

The symptoms can include epigastric pain and nausea. Gastric lavage will remove any unabsorbed Inflamax Paediatric

Suspension, if recently taken and electrolites may be corrected by intravenous infusions, if necessary.

- **Possible Side effects**

Most people will not have problems, but some may get some.

If your child gets any of these serious side effects, stop giving the medicine. See a doctor at once:

- Your child is sick and it contains blood or dark particles that look like coffee grounds
- Pass blood in their stools or pass black tarry stools
- Tiredness or severe exhaustion, changes in the blood which may cause unusual bruising or unexplained bleeding and an increase in the number of infections that they get (e.g. sore throats, mouth ulcers, flu-like symptoms including fever)

- Stomach problems including pain, indigestion or heartburn
- Unexplained wheezing (asthma), worsening of existing asthma, difficulty in breathing, swelling of the face, tongue, neck or throat, fast heart rate, feeling faint or dizzy or collapse (severe allergic reactions)
- Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering and lesions of the skin)
- Meningitis (e.g. stiff neck, fever, disorientation)
- High blood pressure, heart failure, (your child may be tired, have difficulty breathing or swollen legs)
- A small increased risk of heart attack or stroke if you take large amounts for a long time
- Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)
- Swellings or ulcers of the stomach
- Kidney problems, which may lead to kidney failure (your child may pass more or less urine, have blood in the urine or cloudy urine, or feel breathless, very tired or weak, have no appetite, or have swollen ankles)
- When your child experience visual disturbances, such as blurred vision, changes in visual colour perception

If your child gets any of the following side effects see your pharmacist or doctor:

- Uncommon, feeling sick or rarely, being sick
- Uncommon, headache

- Rarely, diarrhoea, constipation and wind, and very rarely, and very rarely, worsening of colitis or Crohn's disease
- Frequency not known, swellings or ulcers of the mouth lining, fluid retention, which may cause swelling of the limbs

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"6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications.

http//www.sahpra.org.za/publications/index/8

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

- **How to store Inflamax Paediatric Suspension**

Store in a well closed container Store at or below 25 0C.

KEEP OUT OF THE REACH OF CHILDREN.

- **Contents of Pack and other information**

Each 5 ml of suspension contains 100 mg of ibuprofen.

Preservatives: Methyl Hydroxybenzoate O,1 % m/v, Propyl Hydroxybenzoate 0,05 % m/v, Sodium Benzoate 0,25 % m/v.

What Inflamax Paediatric Suspension looks like

An orange flavoured, orange coloured syrupy suspension.

100 ml or 200 ml amber glass bottles or 2,5 L brown plastic bottle.

Holder of the certificate of Registration

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