

**PATIENT INFORMATION LEAFLET (PIL)  
TEMPLATE**

PATIENT INFORMATION LEAFLET: INFORMATION  
FOR THE USER

Keuron 100mg/5ml suspension

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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

In this leaflet:

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

**1. WHAT KEURON SUSPENSION 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) which act to relieve pain, swelling (inflammation) and reduce fever.

It can be used for the fast, effective relief of mild to moderate pain such as teething pain, toothache, other dental pain, sore throat, headaches, minor aches and sprains and rheumatic and muscular pain. It can also be used to relieve the symptoms of colds and flu and to reduce fever, including fever after vaccination at 3 months of age.

**2. WHAT YOU NEED TO KNOW BEFORE YOU GIVE KEURON SUSPENSION**

**Before you give this medicine**

This medicine can be given to children from the age of 3 months. 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 3 months old**, or weighs less than 5 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 with a daily dose above 75 mg**, or other non-steroidal anti-inflammatory medicines (aspirin should not generally be given to children under 16, but doctors may occasionally prescribe it)

**Talk to your pharmacist or doctor:**

- If your child has asthma, a history of asthma or other allergic disease
- If your child has bowel problems, or Crohn's Disease
- If your child has other kidney, heart or liver problems (see above)
- If your child has connective tissue disorders such as SLE (Systemic Lupus Erythematosus)
- If your child has chickenpox
- If your child is on a low salt (sodium) diet (this medicine contains 11 mg of sodium per 5 ml spoonful)
- If your child has had a stroke, or has heart problems, high blood pressure, diabetes, high cholesterol – see '**Risk of heart attack or stroke**' in 'Other important information'

### If your child takes other medicines

Before you give this medicine, make sure that you tell your pharmacist about ANY other medicines you might be giving to the child at the same time, particularly the following:

- Other pain killers (including NSAIDs)
- Aspirin 75 mg (to prevent heart attacks or strokes) – the protection may be reduced when you take ibuprofen
- Medicines to thin the blood (e.g. warfarin)
- Water tablets (diuretics), medicines to treat high blood pressure, medicines for heart problems
- Corticosteroids (for pain and swelling)
- Lithium (for bipolar disorder)
- Methotrexate (for cancer, psoriasis or rheumatism)
- Zidovudine (for HIV infection)
- Quinolone antibiotics (for infection)
- Medicines for depression (including SSRIs)
- Ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for your child, including herbal and homeopathic remedies.

### Other important information

**Risk of heart attack or stroke:** Ibuprofen may increase the risk if your child takes large amounts for a long time. The risk is small. Give the lowest amount for the shortest possible time to reduce this risk.

### 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.

**If you smoke** talk to your pharmacist or doctor before you take this medicine (see “Risk of heart attack or stroke” above).

**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.

Do not take this medicine if you have taken mifepristone (for termination of pregnancy) in the last 12 days.

### 3. HOW TO GIVE KEURON SUSPENSION

Check if the cap seal is not broken before first use. If it is, do not give the medicine.

It is important to **shake the bottle** for at least 10 seconds before use.

Always use the plastic spoon supplied with the pack. The spoon can be used to measure 2.5 ml or 5 ml.

Give this medicine to your child to swallow.

6 months-2 years: 2.5 ml, 6-8 hourly

3-7 years: 5 ml, 6-8 hourly

8-12 years: 10 ml, 6-8 hourly

### Don't give more often than every 4 hours

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

If symptoms **worsen** at any time, talk to your doctor.

**For a child of 3 to 6 months of age**, if symptoms do not go away within 24 hours talk to your doctor.

**For a child of 6 months of age and over**, if symptoms do not go away within 3 days talk to your doctor.

### For fever relief after vaccination at 3 months of age:

Give 2.5 ml. Give a second 2.5 ml after 6 hours, if you need to. Don't give any more medicine. See your doctor if fever continues.

Do not give more than the amount recommended above.

Do not give to children under 3 months of age.

After use replace the cap on the top of the bottle tightly. Store all medicines out of the sight and reach of children.

Wash the graduated spoon in warm water and allow to dry.

**If you give too much:** Talk to a doctor straight away. Take the medicine and this leaflet with you.

#### 4. 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:

1. Your child is sick and it contains blood or dark particles that look like coffee grounds
2. Pass blood in their stools or pass black tarry stools
3. 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)
4. Stomach problems including pain, indigestion or heartburn
5. 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)
6. Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering and lesions of the skin)
7. Worsening of existing severe skin infections (you may notice a rash, blistering and discolouration of the skin, fever, drowsiness, diarrhoea and sickness), or worsening of other infections including chicken pox or shingles
8. Meningitis (e.g. stiff neck, fever, disorientation)
9. High blood pressure, heart failure, (your child may be tired, have difficulty breathing or swollen legs)
10. A small increased risk of heart attack or stroke if you take large amounts for a long time
11. Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)
12. Swellings or ulcers of the stomach
13. 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)

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, 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

**If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.**

#### 5. HOW TO STORE KEURON SUSPENSION

Do not store above 30°C.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Do not use Keuron suspension after the expiry date which is stated on the bottle label after EXP. The expiry date refers to the last day of that month.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Keuron suspension contains

The active substance is ibuprofen.

Each 5 ml of oral suspension contains Ibuprofen 100 mg, which is the active ingredient.

The other ingredients are: sugar, glycerine, citric acid, sodium citrate, methyl paraben, propyl paraben, xanthan gum, cremophore, egg yellow and raspberry flavor

**What Keuron suspension looks like and contents of the pack:**

Keuron Suspension is packaged in 100ml amber glass bottles covered with a tamper evident plastic cap. The pack contains 100 ml of pale-yellow, raspberry-flavoured syrupy suspension.

##### Manufacturer

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