**Patient Information Leaflet**

PEDIFEN**® Pediatric Suspension**

Ibuprofen 400 mg

**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.

1. **What is PEDIFEN® Pediatric Suspension and what it is used for**

PEDIFEN® Pediatric Suspension contains Ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), used to reduce mild to moderate pain and inflammation, and for the symptomatic treatment of rheumatoid arthritis, osteoarthritis, and period pain. PEDIFEN® Pediatric Suspension is used to treat pain, fever and the symptoms of juvenile arthritis in children older than 6 months of age (ATC code: M01AE).

1. **What you need to know before you take PEDIFEN® Pediatric Suspension**

***Do not take PEDIFEN® Pediatric Suspension if you***

* are allergic (hypersensitive) to ibuprofen, aspirin, any other NSAID, or any of the other ingredients (listed in section 6),
* have or have had a stomach ulcer, perforation or bleeding,
* suffer from severe liver, kidney or heart failure.

***Talk to your doctor or pharmacist if you***

* have a bleeding disorder,
* have high blood pressure,
* have heart problems or suffered from a previous stroke or think that you might be at risk of these conditions (for example, if you have, diabetes, high cholesterol or are a smoker).

Medicines such as PEDIFEN® Pediatric 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.

* There is a risk of renal impairment in dehydrated children and adolescents, especially in case of fever. It is important to hydrate sufficiently children under Pedifen treatment.

***Interactions with other medicines*  
Do not use the medicine if you are** taking other NSAID pain killers or aspirin with a daily dose above 75mg.  
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines (including medicines obtained without prescription), particularly, ***if you are taking:***

* blood thinning drugs (anticoagulants e.g.warfarin) drugs to prevent clotting (anti platelet drugs e.g. aspirin);
* drugs to help you passing water (diuretics);
* drugs to treat high blood pressure (e.g. captopril, atenolol, losartan);
* drugs to treat mania and depression (lithium and SSRI);
* corticosteroids (to treat allergic or inflammatory disorders);
* drugs to treat HIV treatment (e.g. Zidovudine);
* drugs used for the temporary suppression of your immune system (e.g. methotrexate, ciclosporin, tacrolimus);
* antibiotics (e.g. ciprofloxacin or aminoglycosides such as gentamycin);
* mifepristone (for pregnancy termination);
* alcohol may increase the risk of stomach irritation.

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

* This medicine belongs to a group of medicines which may impair fertility in women. This effect goes away when the medicine is stopped. It is unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant.
* Do not take PEDIFEN® Pediatric Suspension if you are in the last 3 months of pregnancy.
* Speak to your pharmacist or doctor before taking this product if you are in the first 6 months of pregnancy or are breast feeding.

***Driving and using machines***

NSAIDs may sometimes cause symptoms such as drowsiness or dizziness which could make it unsafe to drive or use machines. If you notice any such symptoms, do not drive or operate machinery and ask your doctor or pharmacist for advice.

1. **How to take PEDIFEN® Pediatric Suspension**

**Always take it exactly as your doctor or pharmacist has told you.**

* **Shake well before each use.**
* **Each 5 ml measure contains 100 mg ibuprofen.**
* Safety and efficacy of ibuprofen in children less than 6 months of age has not been established.
* *As anti-fever:* the dosage in children between 6 months to 12 years of age depends on the body temperature:

|  |  |
| --- | --- |
| Initial body temperature | recommended dosage |
| below 39.2ºC | **5 mg/kg** |
| above 39.2ºC | **10 mg/kg** |

These doses may be repeated every 6-8 hours. The duration of the antifever effect of a dose is 6-8 hours.

Maximum daily dosage should not exceed 40 mg/kg.

* *As anti-pain:* the dosage in children between 6 months to 12 years of age is **10 mg/kg every 6 - 8 hours**.

Maximum daily dose should not exceed 40 mg/kg.

Times of administration should be so planned as to not disturb the sleep of the child.

* *Juvenile inflammation:* the dosage is **30 - 40 mg/kg per day** (in light cases 20 mg/kg per day may be sufficient)

This dosage should be divided into 3-4 equal portions and administered at equal time intervals.

* *Individualization of dosage:* the dosage should be adjusted individually according to the need of the patient.

Dosage can be increased or decreased between recommended limits depending on the severity of symptoms.

After desired clinical response is obtained, remission can be maintained at a reduced dosage level.

If the patient has both fever and pain, the dosage should be so chosen as to treat most severe symptom effectively.

In juvenile arthritis therapeutic response is observed in a period of time ranging from few days to few weeks.

* If you take more PEDIFEN® Pediatric Suspension than you should please contact a doctor immediately or go to the nearest hospital.
* If you miss a dose, leave it out and take the next dose whenever it is due. After that, just carry on as before.

1. **Possible side effects**

Like all medicines, ibuprofen can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body), severe blistering or peeling of the skin should be reported to a doctor immediately.

***STOP TAKING this medicine and tell your doctor if you experience:***

* Persistent sickness, or feeling sick, heartburn, constipation or diarrhoea.
* Abdominal pain, bringing up blood or passing black stools, sore mouth or swelling of the mouth or tongue.
* Swelling of the ankles or any other parts of the body.
* Passing too much or too little urine.
* Problems with your eyesight or noises in the ears.
* Headaches, dizziness, drowsiness or feeling abnormally tired.
* Tingling in the fingers or toes, or other odd sensations.
* Feeling depressed or confused, or imagining things that are not really there.
* An unexplained fever or persistent sore throat, bruising of the skin, or any signs of anemia (such as faintness or feeling very tired).
* Yellowing of the skin or whites of the eyes.
* Skin irritation or rash due to sunlight.

Medicines such as ibuprofen may be associated with a small increased risk of heart attack (‘myocardial infarction’) or stroke.

Other rare side effects include confusion, depression, dizziness and vertigo (spinning sensation), blood disorders, kidney problems, inflammation of the bowel (colitis), inflammation of the stomach lining (gastritis), or Crohn’s disease. Ibuprofen can reduce the number of certain types of blood cells. If you have any blood tests carried out, remember to tell the doctor that you are taking ibuprofen. PEDIFEN® Pediatric Suspension may also cause your blood pressure to increase.

CONSULT YOUR DOCTOR IF YOU NOTICE AN UNDESIRABLE EFFECT.

1. **How to store PEDIFEN® Pediatric Suspension:** Store below 30°C, in the original package, protected from light. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.
2. **Other information**

**What PEDIFEN® Pediatric Suspension contains:** Each 5 ml measure contains 100 mg ibuprofen. **List of excipients:** methyl hydroxybenzoate, propyl hydroxybenzoate, saccharose, citric acid, sodium benzoate, agar-agar, glycerine, sorbitol, kaolin, polysorbate 80, sunset yellow FC Edicol, orange flavour, purified water.

**PEDIFEN® Pediatric Suspension** is presented in a cardboard box containing 1 bottle of 100 ml.

**PEDIFEN® Pediatric Suspension** is a non prescription medicine.

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