PEDIFEN®

ibuprofen

SUSPENSION FOR CHILDREN – TABLETS FOR ADULTS

Non-steroidal anti-inflammatory with analgesic, antipyretic and anti-inflammatory properties.

PEDIFEN® Pediatric Suspension is indicated for the symptomatic treatment of pain, fever and juvenile arthritis in children over 6 months.

PEDIFEN® Adult is indicated for: relief of mild to moderate pain, treatment of primary dysmenorrhea, symptomatic treatment of rheumatoid arthritis and osteoarthritis.

INDICATIONS AND DOSAGE

Indication	Unit dose	Frequency
Paediatric Syrup (100mg / 5ml)		
Symptomatic treatment of fever	Temperature < 39,2°C : 5mg/kg	Every 6 - 8 hours
	Temperature >39,2°C : 10mg/kg	Every 6 - 8 hours
Symptomatic treatment of pain	10mg/kg	Every 6 - 8 hours
Juvenile arthritis	10mg/kg	Every 6 - 8 hours
DOSE LIMIT: Children should not be given more than 40mg/kg per 24 hours		
Tablets for adults (400mg)		
Relief of mild to moderate pain	400mg	4 - 6 times a day
Primary dysmenorrhea	400mg	Every 4 hours
Symptomatic treatment of rheumatoid arthritis and osteoarthritis	400mg - 800mg	3 - 4 times a day

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ibuprofen

EUROPEAN GMP

WHENEVER IT HURTS, FOR ALL AGES!

analgesic, antipyretic & anti-inflammatory

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AVANTAGES – POINTS CLEFS

- **PEDIFEN®** is a substance from the class of non-steroidal anti-inflammatory drugs with analgesic, antipyretic and anti-in flammatory properties.
- **PEDIFEN®** is at your disposal:
  - In two oral galenic formulations: tablets and paediatric syrup.
  - In packs of 30 tablets or bottles of 100ml.
- The paediatric syrup of **PEDIFEN®** has a very appealing orange taste, specifically developed in order to increase therapy compliance.
- **PEDIFEN®** is the best tolerated drug of its class: the side effects seem to depend on the dosage and the duration of the treatment.*
- **PEDIFEN®** possesses one of the best gastro-intestinal tolerability profiles: it is associated with the lowest risk for gastro-intestinal complications in comparison with other NSAID's.**
- **PEDIFEN®**: for whenever it hurts, for all ages, with the inherent quality of Dafra: European fabrication according to European GMP standards.

PHARMACODYNAMIC PROPERTIES

Ibuprofen is a substance from the class of non-steroidal anti-inflammatory drugs (NSAIDs) with analgesic, antipyretic and anti-inflammatory properties. Ibuprofen acts by inhibiting cyclooxygenase, an enzyme which controls prostaglandin synthesis. Since prostaglandins are important mediators of pain, fever and inflammatory reactions, their inhibition promotes remission of these symptoms.

(*) Moore N.J.R. Soc Med. 2007;100 (suppl 48):2-6
(**)Bjarnason I.J.R. Soc Med. 2007; 100 (suppl 48): 11-14

PHARMACOKINETIC PROPERTIES

Ibuprofen is a racemic mixture of (-)R and (+)S isomers. Of these, only (+)S isomer has clinical activity. (-)R isomer acts as a reservoir in the circulation by continuous interconversion to (+)S isomer. **Absorption**: Ibuprofen is well absorbed after oral administration and produces peak plasma concentrations in 1 to 2 hours. In febrile children following a dose of 10 mg/kg, observed Cmax and Tmax values are 55 mcg/ml and 0,97 hour respectively. Absorption is most rapid when **PEDIFEN®** Adult is taken on an empty stomach. In the presence of food Tmax is delayed and Cmax reduced but AUC remains unchanged. Distribution: The drug is 99% bound to plasma proteins. The volume of distribution is 0,2 L/kg in children (≤11 years of age) and 0,12 L/kg in adults. **Metabolism**: Most of the administered dose is excreted in the urine after having been first converted into metabolites in the liver. **Elimination**: Elimination of ibuprofen is rapid. After the last dose elimination is completed within 24 hours. The drug has a half life of approximately 2 hours and a biphasic plasma elimination curve.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Chronic administration of nonsteroidal anti-inflammatory agents, especially at high doses, may be complicated by gastrointestinal ulcer, bleeding or perforation without warning signs. In patients with reduced renal perfusion, nonsteroidal anti-inflammatory drugs may cause acute renal failure by lowering supportive role of renal prostaglandins in maintaining renal circulation. This risk is present in patients with reduced renal, hepatic and cardiac functions and in patients who are taking diuretics. This effect of NSAIDs is reversible and disappears after discontinuation of treatment. Ibuprofen may cause salt and water retention and edema. It should be used with caution in patients with heart failure and hypertension. Although of brief duration and reversible, ibuprofen has anti-aggregative effect on thrombocyte function. It should be used with caution in patients with a bleeding disorder or in those who are taking anticoagulant medication. Coagulation parameters should be monitored closely. As ibuprofen is mainly eliminated via the kidney, it may accumulate in the body of patients with reduced renal function. These patients should be followed closely and dosage should be reduced when necessary. Liver function test elevations (ALT, AST) may occur during therapy. If they are increasing or clinical symptoms of liver disease are present, ibuprofen treatment should be discontinued. If, during therapy, the patient complains of blurred vision or difficulty of discriminating colors, treatment should be discontinued.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy Category B: Animal reproduction studies have not shown any teratogenic effect of ibuprofen on the fetus. However adequate and well- controlled studies in pregnant women have not been done. NSAIDs may cause premature closure of ductus arteriosus when administered towards the end of the pregnancy. **PEDIFEN®** Adult is not recommended for use in pregnant women. Use in lactation: It is not known whether ibuprofen passes into human milk. However, in view of the potential adverse effects of NSAIDs on the infant either nursing or ibuprofen treatment should be discontinued.

UNDESIRABLE EFFECTS

Controlled studies have indicated that the frequency of side effects observed with ibuprofen is only half those observed with acetylsalicylic acid and indomethacin. Most frequently reported side effect occurring in more than 1% of patients are: Nausea, epigastric pain, burning in the stomach, diarrhea, constipation, flatulence, edema, dizziness, skin rash, pruritus, tinnitus. Less frequently reported side effects occurring in less than 1% of patients include: Anaphylactoid reaction, heart failure, hypertension, gastric and duodenal ulcer, gastrointestinal hemorrhage, gastritis, duodenitis, esophagitis, hepatitis, jaundice, anemia, thrombocytopenia, depression, convulsion, aseptic meningitis, erythema multiform, Stevens-Johnson's syndrome, Lyell's syndrome, acute renal failure, renal papillary necrosis, tubular necrosis, glomerulitis, amblyopia. IN CASE OF AN UNEXPECTED SIDE EFFECT, CONSULT YOUR PHYSICIAN.

OVERDOSE

If the patient is seen immediately after the ingestion of medication, emesis is induced or gastric lavage is performed. Administration of activated carbon slurry may be beneficial by decreasing absorption and reabsorption of medication. No specific antidote is known to ibuprofen. Treatment is supportive and symptomatic.

For the complete SMPC, please visit www.dafrapharma.com