

Pediafen[®]

100 mg/5 mL Suspension

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about PEDIAFEN

Each 5 mL of Pediafen oral suspension contains 100 mg ibuprofen.

The excipients are: sucrose, xanthan gum, sodium benzoate, strawberry and erythrosine.

Ibuprofen is an anti-inflammatory drug that has analgesic, antipyretic and anti-inflammatory properties. It works by inhibiting synthesis of prostaglandins that cause inflammation and pain in the body.

PEDIAFEN is used for the reduction of fever and relief of minor aches and pains due to common colds, flu, sore throat, headaches, toothaches or other inflammatory conditions.

PEDIAFEN is also recommended in juvenile rheumatoid arthritis.

The way to take PEDIAFEN

Take PEDIAFEN as directed by your physician. The dose should be taken after meals or milk. The usual recommended dosage for fever is 5 to 10 mg/kg/dose (depending on the severity of fever) and for pain 10 mg/kg/dose; doses may be given every 6-8 hours up to a maximum daily dose of 40 mg/kg.

Infants (< 1 year): the dose is decided by the doctor.

Children (1-2 years): 3.75 mL 3 to 4 times daily.

Children (2-3 years): 5 mL 3 to 4 times daily.

Children (4-5 years): 7.5 mL 3 to 4 times daily.

Children (6-8 years): 10 mL 3 to 4 times daily.

Children (9-10 years): 12.5 mL 3 to 4 times daily.

Children (11-12 years): 15 mL 3 to 4 times daily.

Children over 12 years and adults may take up to 20 mL, 3 times daily.

For the treatment of juvenile rheumatoid arthritis, the usual recommended dose is 30-40 mg/kg/day in 3 divided doses.

Duration of treatment

Take PEDIAFEN at the recommended dose, as long as symptoms persist.

If your child does not get better, or pain or fever gets worse or persist for more than 3 days, or if any new symptoms appear, consult your doctor.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Administer the missed dose to your child as soon as you remember unless the next intake is near. Go on giving the next scheduled dose as directed. Do not administer a double dose at once.

Contraindications

This drug is contraindicated in case of hypersensitivity to ibuprofen, aspirin, or other anti-inflammatory agents.

Precautions

-This drug should be used with caution in children having asthma, peptic ulcer, hepatic or renal insufficiency or hemophilia.

-Do not use this medication with any other product that contains ibuprofen, or other pain reliever/fever reducer, unless directed by a doctor.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Concomitant administration of this medication with other anti-inflammatory drugs should be avoided.

Adverse reactions

This drug is usually well tolerated. Occasionally reported adverse effects were minor: skin rash, abdominal or stomach pain, heartburn, dizziness and nausea.

Please inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children. Shake bottle well before use.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

PEDIAFEN suspension, ibuprofen 100 mg /5 mL, bottle of 100 mL with a dosing cup.

Revision date: 05/2023

PEDN1/004