Pedifen®

Ibuprofen Oral Suspension BP

Composition:
Each 5ml contains:
Ibuprofen BP 100mg
Flavoured Syrup Base ..... q.s.
Approved colour used.

Pharmaceutical Form :
Oral liquid

Therapeutic indications:
Children aged 3 months to 12 years:
Mild to moderate pain, post-immunisation pyrexia, rheumatic or muscular pain, headache, reduction of fever, sore throat, teething pain, toothache, minor aches and pains, symptoms of cold and influenza.

Posology:
Children aged 3 months to 12 years:
Not recommended for children weighing less than 5 kg. For pain and fever – 20mg/kg/day in divided doses.

Infants 3-6 months : 2.5 ml three times a day. Do not use for more than 24 hours.
Infants 6-12 months : 2.5 ml three times a day.
Children 1-2 years : 2.5 ml three to four times a day
Children 3-7 years : 5 ml three to four times a day
Children 8-12 years : 10 ml three to four times a day
Doses should be taken every 6 – 8 hours when required, and at least 4 hours should be left between doses.

Post-immunisation fever:
2.5 ml (50 mg) followed by one further dose of 2.5 ml (50mg) six hours later if necessary. No more than 2 doses in 24 hours.
If fever is not reduced, consult a doctor.
Do not give to children under 3 months of age.
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.
For children aged ≥ 3 months to ≤ 5 months: if the child's symptoms worsen or if the symptoms persist for more than 24 hours, consult a doctor
For children aged 6 months and over: if symptoms worsen or if the symptoms persist for more than 3 days, consult a doctor.

Mode and route of administration: Oral

Indication of the most favorable time for administration of the Drug: Not known

Contraindications:
- Hypersensitivity to Ibuprofen or to any of the excipients.
- Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs.
- Active or history of recurrent peptic ulcer / haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
- History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
- Severe heart failure (NYHA Class IV), renal failure or hepatic failure.
- Last trimester of pregnancy.

Undesirable effects:
Hypersensitivity reactions have been reported and these may consist of:
a) non-specific allergic reactions and anaphylaxis,
b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm or dyspnoea,
c) various skin reactions, e.g. pruritus, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).
The following list of adverse effects relates to those experienced with Ibuprofen at OTC doses, for short-term use.
In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.
- Blood & lymphatic system disorders
- Immune system disorders
- Nervous system disorders
- Cardiac disorders
- Gastrointestinal disorders
- Hepatobiliary disorders
- Skin and subcutaneous tissue disorders
- Renal and urinary disorders

Drug interactions:
Aspirin / Acetylsalicylic acid: Unless low-dose aspirin (not above 75mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions.
Other NSAIDs including cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse effects.
Ibuprofen should be used with caution in combination with:
- Anti-coagulants
- Anti-hypertensives and diuretics
- Corticosteroids
- Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs)
- Cardiac glycosides
- Lithium
- Methotrexate
- Ciclosporin
- Mifepristone
- Tacrolimus
- Zidovud

Special warnings and precautions for use:
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to relieve symptoms.
The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation, which may be fatal.
Masking of symptoms of underlying infections: This medicine can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection.
Respiratory: Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.
Other NSAIDs: The use of ibuprofen with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.
SLE and mixed connective tissue disease:
Systemic lupus erythematosus and mixed connective tissue disease – increased risk of aseptic meningitis.
Renal: Renal impairment as renal function may further deteriorate.
Hepatic: Hepatic dysfunction
Cardiovascular and cerebrovascular effects: Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.
Avoid use immediately before or after heart surgery.
Caution should be exercised in patients taking a diuretic.
Impaired female fertility: There is limited evidence that drugs which inhibit cyclooxygenase / prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment. The use of Ibuprofen is therefore not recommended in women attempting to conceive.
Gastrointestinal: NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated.
The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation and in the elderly. These patients should commence treatment on the lowest dose available.
Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.
Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin.
Caution should be taken when using ibuprofen with excessive alcohol or heavy alcohol drinkers. Alcohol may increase the risk of gastrointestinal bleeding.
Where GI bleeding or ulceration occurs in patients receiving Ibuprofen, the treatment should be withdrawn.
Immune System: Ibuprofen may cause severe allergic reactions including very rare cases of anaphylaxis. Symptoms may include hives, facial swelling, asthma (wheezing), shock, skin reddening, rash or blisters. If any of these symptoms occur, patients should stop use and seek medical help right away.
Dermatological: Serious skin reactions, some of them fatal, including exfoliative dermatitis, erythema multiforme, Stevens-Johnson Syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Acute generalised exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. Ibuprofen should be discontinued at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity.
Dehydration: There is a risk of renal impairment in dehydrated children.
Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Pregnancy and Lactation:
Pregnancy:
During the first and second trimester of pregnancy, this medicine should not be given unless clearly necessary. If this medicine is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.
This medicine is contraindicated during the third trimester of pregnancy.
Lactation:
Ibuprofen appears in breast milk in very low concentration and is unlikely to affect breast-fed infants adversely.

Effect on geriatrics and patients with special pathologies: Not known.

Effects on ability to drive and use machines: Not known.

Attitude to be taken in case of omission of one or more doses:
If you forget a dose, give the next dose when needed, provided that the last dose was taken at least 4 hours ago. Do not take a double dose.

Overdose:
Symptoms:
Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, abdominal pain or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as lethargy and drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions.
In serious poisoning metabolic acidosis may occur and the prothrombin time/ INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Rhabdomyolysis, hypothermia and apnoea (primarily in children) may also rarely occur. Cardiovascular toxicity, including hypotension, cardiac arrhythmias, including ST-segment and T-wave changes, have been reported; ventricular tachycardia/ventricular fibrillation cardiac arrest, and prolonged QTc occurred in fatal cases.
Management:
Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

Storage:
Store below 30°C in dry place, protect from light.
Kee the medicines out of reach of children.

If you notice side effects not mentioned in this leaflet, it is advised to notify your doctor or health care professional.

Presentation: Box of 1 bottle of 100 ml with pack insert.

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