

ibufen oral suspension

ibuprofen 100 mg/5 ml

Read all of this leaflet carefully because it contains important information for you:

This medicine is available without prescription. However, you still need to take ibufen oral suspension carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 5 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet :

1. What **ibufen oral suspension** is and what it is used for.
2. Before you take **ibufen oral suspension**.
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1. WHAT ibufen oral suspension IS AND WHAT IT IS USED FOR

Ibuprofen belongs to the group of drugs called non-steroidal anti-inflammatory drugs (NSAIDs). This medicine is used to treat: mild or moderate pain, fever and juvenile rheumatoid arthritis.

2. BEFORE YOU TAKE ibufen oral suspension

Do not take ibufen oral suspension:

If you are allergic to ibuprofen or any of the other ingredients of ibufen oral solution. If you have had allergic reactions of an asthmatic type, rhinitis or hives when taking aspirin or other medicines in the group of non-steroidal anti-inflammatory drugs. If you have a gastrointestinal ulcer or gastrointestinal bleeding. If you have an inflammatory bowel disease, such as ulcerative colitis or Crohn's disease. If you suffer from severe liver or kidney failure. If you suffer from a blood clotting disorder. If you are pregnant. (see section "Pregnancy").

Take special care with ibufen oral suspension:

If you have had a gastrointestinal disease, such as ulcer and inflammatory gastrointestinal disease. If you experience a digestive disorder such as pain or bleeding, discontinue treatment and talk to your doctor. If you suffer from a liver or kidney disease. If you have heart failure or high blood pressure. If you suffer from bronchial asthma or an allergic disease.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take ibuprofen with other analgesics without asking your doctor.

Patients on continuous treatment with other medicines (anticoagulants and platelet aggregation inhibitors, methotrexate, lithium, mifepristone, digoxin and cardiac glycosides, antihypertensives and diuretics, phenytoin, probenecid, sulfapyrazone, oral antidiabetics, corticoids, zidovudine) should ask their doctor before taking this or any other analgesic.

Pregnancy and Breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take ibuprofen during pregnancy, particularly during the third trimester, as it could be dangerous for the foetus.

Although only small amounts of ibuprofen pass through to nursing milk, it is not recommended to take ibuprofen for long periods while breast-feeding.

Driving and using machines:

If you suffer from light-headedness, dizziness, visual disturbances or other symptoms while taking this medicine, do not drive or use machines. If you only take a single dose of ibuprofen or for a short period, no special precautions need to be taken.

Important information about some of the ingredients of ibufen oral suspension:

One of the ingredients of this medicine is glycerol. It can be harmful at high doses. It may cause headache, stomach ache and diarrhoea.

Since it contains sodium benzoate (E211) as an excipient, it may irritate the eyes, skin, and mucous membranes slightly. It may also increase the risk of a yellowish colouring of the skin (jaundice) in newborns.

This medicine contains maltitol syrup, so if you are intolerant to any sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE ibufen oral suspension

Always take ibufen oral suspension exactly as your doctor has told you. You should check with your pharmacist if you are not sure. The usual dose is:

6-12 ^{years}	1-3 ^{years}	4-6 ^{years}	7-9 ^{years}	10-12 ^{years}	+12 ^{years}
7,7-9 Kg	10-15 Kg	16-20 Kg	21-29 Kg	30-40 Kg	+40 Kg
					
3-4 par jour per day	3 par jour per day	3 par jour per day	3 par jour per day	3 par jour per day	3-4 par jour per day

ibufen oral suspension is a suspension for oral administration. For an accurate dose, the packages contain a metered 5 ml oral syringe. Clean and dry the syringe after each use. If you have a sensitive stomach, take the medicine at meal times. **Elderly:** No special dose changes are generally required. **Patients with kidney or liver failure:** Your doctor will adjust the dose.

If you take more ibufen oral suspension than you should:

If you have taken more **ibufen oral suspension** than you should, talk to a doctor or pharmacist immediately.

The most common symptoms which could occur in the event of overdose are: abdominal pain, nausea, vomiting, drowsiness, headache, involuntary eye movements, tingling in the ears, and lack of coordination in muscle movements. More severe symptoms can occur rarely, including gastrointestinal bleeding, blood pressure lowering, seizures, and respiratory disorders.

In the event of overdose or accidental swallowing, go to a medical centre stating the medicine and the amount taken.

If you forget to take ibufen oral suspension:

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **ibufen oral suspension** can cause side effects, although not everybody gets them. The side effects of medicines like ibuprofen are more common in people over 65 years of age. The incidence of adverse events is lower in short treatments and if the daily dose is below the recommended maximum dose.

The following adverse effects have been observed:

Gastrointestinal:

Very common: digestive disorders, diarrhoea.

Common: nausea, vomiting, abdominal pain.

Uncommon: bleeding, stomach or duodenal ulcers, mouth ulcers.

Rare: gastric or intestinal perforation, flatulence, constipation, inflammation of the oesophagus and bowel ulcers or inflammation.

Skin and allergic reactions:

Common: skin rash.

Uncommon: skin reddening, skin itching or swelling, swelling of the lips, face or tongue, increased nose secretion and breathlessness.

Rare: severe allergic reactions (anaphylactic shock).

Very rare: severe skin itching of sudden onset, or skin blisters, pain in the joints and fever (lupus erythematosus), hair loss, skin reactions caused by light.

Central nervous system:

Common: tiredness or drowsiness, headache, light-headedness, dizziness.

Uncommon: insomnia, anxiety, restlessness, visual disturbances, tingling in the ears.

Rare: disorientation or confusion, agitation, irritability, depression, abnormal or blurred vision, and hearing problems.

Very rare: aseptic meningitis.

Blood:

Very rare: prolongation of bleeding time, white blood cell reduction (it may occur

as an appearance of more frequent infections with fever, shivering or sore throat), red blood cell reduction (it may occur as breathlessness and skin pallor).

Cardiovascular:

Swelling of the limbs or fluid retention in the arms or legs (more likely to occur in people with high blood pressure or kidney problems). Heart failure or high blood pressure (hypertension), particularly in the elderly.

Kidney:

Kidney disorders or failure.

Liver:

Rare: hepatitis (liver inflammation) and jaundice (yellow skin colour).

Other:

Worsening of inflammation during infectious conditions.

To date no severe allergic reactions have been reported with ibuprofen, though they cannot be ruled out. Manifestations of this type of reaction include fever, skin rash, abdominal pain, severe and persistent headache, nausea, vomiting, swelling of the face, tongue and throat, breathlessness, asthma, palpitations, low blood pressure, or shock.

If any of the above adverse events occur, stop treatment and tell your doctor immediately: Allergic reactions including skin rash, swelling of the face, wheezing or breathlessness. Blood vomiting or vomiting that looks like coffee dregs. Bloody stools or bloody diarrhoea. Severe pain in the stomach. Significant skin blisters or shedding. Severe or persistent headache. Yellow skin colour (jaundice). Signs of severe hypersensitivity (see above). Swelling of the limbs or fluid retention in the arms or legs.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ibufen oral suspension

This medicinal product does not require any special storage conditions.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Do not use ibufen oral suspension after the expiry date which is stated on the carton.

6. FURTHER INFORMATION

What ibufen oral suspension contains:

- The active substance is ibuprofen. Each 5 ml of oral suspension contains 100 mg of ibuprofen.

- The other ingredients are glycerol, maltitol syrup, microcrystalline cellulose, xanthan gum, anhydrous citric acid, sodium citrate, sodium benzoate (E211), polysorbate 80, sodium saccharine, orange flavour, and purified water.

ibufen oral suspension is a white oral suspension. It is supplied in 100 ml and 200 ml packages with a metered 5 ml oral syringe.

Marketing Authorisation Holder and Manufacturer:

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