

PACKAGE LEAFLET: Information for the patient

FASDOL

Oral suspension – 100 mg / 5 ml

(Ibuprofen)

Read this leaflet carefully before you start giving this medicine to your child 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fasdol is and what it is used for
2. What you need to know before you take Fasdol
3. How to take Fasdol
4. Possible side effects
5. How to store Fasdol
6. Other information

1. WHAT FASDOL IS AND WHAT IT IS USED FOR

Fasdol contains the active substance ibuprofen.

Ibuprofen is a propionic acid derivative with anti-inflammatory, analgesic and antipyretic properties. Fasdol is used:

- to reduce fever;
- in the management of mild to moderate pain and inflammation.

Your doctor may have given Fasdol to your child for another purpose. Ask your doctor if you want to know why your child was given this medication.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FASDOL

Do not give Fasdol to your child if the child:

- is allergic to ibuprofen or to any of the excipients of Fasdol;
- has a history of asthma attack, angioedema, urticaria and rhinitis after taking aspirin or any other non-steroidal anti-inflammatory drug;
- is under 2 years old;
- suffers from severe hepatic, renal or heart impairment;
- has a history of gastrointestinal bleeding or perforation, related to previous therapy with nonsteroidal antiinflammatory drugs;
- has active or previous peptic ulceration;
- has had a repeating gastrointestinal ulceration or bleeding (two or more distinct episodes of ulceration or haemorrhage).

If this medicinal product will be used by adults, it should not be used in the last trimester of pregnancy or during breastfeeding.

Take special care with Fasdol

Ask your doctor or pharmacist before you give Fasdol to your child.

Non-selective non-steroidal anti-inflammatory drugs are associated with a small increased risk of thrombotic events even when used short-term in those with no cardiovascular risk factors. High doses of non-steroidal anti-inflammatory drugs are associated with an increased risk of thrombotic events.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss the treatment with your doctor or pharmacist before giving Fasdol to your child if the child:

- has heart problems including heart failure, angina (chest pain), or has had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”);
- has high blood pressure, diabetes, high cholesterol, has a family history of heart disease or stroke;
- has an infection – please see heading “Infections” below.

Caution is required if the medicinal product will be used by adults who are smokers.

Non-steroidal anti-inflammatory drugs should be used with caution in patients with hepatic impairment, because there is an increased risk of gastrointestinal bleeding and fluid retention.

Non-steroidal anti-inflammatory drugs also should be used with caution in the elderly (risk of serious side effects and fatalities), and in patients with allergic disorders, coagulation defects and connective-tissue disorders.

Non-steroidal anti-inflammatory drugs should be used with caution in patients with renal impairment (the lowest effective dose should be used for the shortest possible duration, and renal function should be monitored). There is a risk of kidney dysfunction in dehydrated patients.

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as their conditions may be exacerbated (see “Possible side effects”).

It is preferable to avoid non-steroidal anti-inflammatory drugs in patients with active or previous gastrointestinal ulceration or bleeding, and to withdraw them if gastrointestinal lesions develop.

The combination of a non-steroidal anti-inflammatory drug and low-dose aspirin can increase the risk of gastro-intestinal side-effects. For this reason, this combination should be used only if absolutely necessary and the patient should be monitored closely.

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately Fasdol and contact immediately your doctor or medical emergencies if you notice any of these signs.

Skin reactions

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Fasdol and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Infections

Fasdol may hide signs of infections such as fever and pain. It is therefore possible that Fasdol may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If your child takes this medicine while he / she has an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.

Fasdol use should be avoided in patients with varicella.

Taking other medicines

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription.

It is particularly important to inform your doctor that the child is taking:

- analgesics, increased side-effects from concomitant use of non-steroidal anti-inflammatory drugs with other non-steroidal anti-inflammatory drugs or aspirin; ibuprofen possibly reduces the antiplatelet effect of aspirin;
- antibacterials, possible increased risk of convulsions when NSAIDs given with quinolones;
- drugs that thin the blood, enhanced anticoagulant effect of coumarins (warfarin), phenindione, enhanced effect of ticlodipine and increased risk of bleeding when given with dabigatran etexilate or heparins;
- antidepressants, increased risk of bleeding when non-steroidal anti-inflammatory drugs given with selective serotonin re-uptake inhibitors (SSRIs) or venlafaxine;
- antidiabetics, possibly enhanced effects of sulfonylureas;
- antifungals, azoles (voriconazole), they moderately increase the exposure to ibuprofen;
- antivirals, plasma concentration of NSAIDs possibly increased by ritonavir; increased risk of haematological toxicity when given with zidovudine;
- ciclosporin, increased risk of nephrotoxicity;
- corticosteroids, NSAIDs increase the risk of gastrointestinal bleeding when given with corticosteroids;
- cytotoxics, non-steroidal anti-inflammatory drugs probably reduce excretion of methotrexate increasing the risk of toxicity; increased risk of bleeding when NSAIDs given with erlotinib;
- diuretics, increased risk of nephrotoxicity of non-steroidal anti-inflammatory drugs and antagonized diuretic effect by non-steroidal anti-inflammatory drugs; possible increased risk of hyperkalaemia when NSAIDs given with potassium-sparing diuretics and aldosterone antagonists;
- lithium, non-steroidal anti-inflammatory drugs reduce excretion of lithium increasing the risk of toxicity;
- pentoxifylline, possible increased risk of bleeding when NSAIDs given with pentoxifylline;
- tacrolimus, possible increased risk of nephrotoxicity when ibuprofen given with tacrolimus;
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers

such as atenolol, angiotensin-II receptor antagonists such as losartan).

Taking Fasdol with food and drinks

If your child has gastro-intestinal disorders, give him / her Fasdol with food or milk. It is not recommended to consume alcohol while using Fasdol.

Pregnancy and breastfeeding

If this medicinal product will be used by adults, the following recommendations should be taken into account.

Pregnancy

Ibuprofen should be avoided during the first and second trimester of pregnancy. Ibuprofen is contraindicated during the third trimester of pregnancy.

Breastfeeding

Ibuprofen and its metabolites are excreted in human breast milk only in very small amounts. Fasdol should not be administered during breastfeeding.

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

Driving and using machines

Adverse effects such as dizziness, drowsiness, fatigue and visual disturbances, may appear after taking Fasdol. In this case, you should not drive or use machines.

Important information about some of the excipients of Fasdol

Fasdol oral suspension contains:

- methyl hydroxybenzoate and propyl hydroxybenzoate, which may cause allergic reactions (possibly delayed);
- very small amounts of ethyl alcohol (ethanol 96%), 19.2 mg in 5 ml;
- sorbitol; if you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving your child this medicinal product;

- 1.4 g sucrose (sugar) / 5 ml; this should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving him / her this medicinal product.

3. HOW TO TAKE FASDOL

Always use Fasdol exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Dosage of ibuprofen must be adjusted carefully according to individual requirements and response using the lowest possible effective dose for the shortest duration necessary to relieve symptoms. If your child has an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).
- Shake the bottle well before use.
- Fasdol should not be used in children under 2 years old.

The recommended daily dose for the treatment of **pain, inflammation** and **fever** in children is 20 mg / kg weight in divided doses, every 6 to 8 hours.

Children 2 – 3 years: 2.5 ml (50 mg) 3 – 4 times a day;

Children 3 – 7 years: 5 ml (100 mg), 3 – 4 times a day;

Children 8 – 12 years: 10 ml (200 mg), 3 – 4 times a day;

Fasdol is given for short treatment. This medicine should not be given for longer than 3 days.

If your child takes more Fasdol than he / she should

If your child takes more Fasdol than he / she should, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

It was concluded that ibuprofen appeared to be much less toxic in acute overdose than either aspirin or paracetamol. Current advice is that doses below 100 mg / kg of ibuprofen are unlikely to cause toxicity in children, whereas clinical features will occur in children who have ingested more than 400 mg / kg of ibuprofen.

If you forget to give your child Fasdol

If you forget to give your child one dose (or more than one dose), give him / her the next dose in its usual time. Do not give a double dose (or higher) to make up for the forgotten dose(s).

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

4. POSSIBLE SIDE EFFECTS

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

Uncommon (may affect up to 1 in 100 users):

- Hypersensitivity with urticaria and pruritus
- Stomach pain
- Nausea
- Indigestion
- Headache

Rare (may affect up to 1 in 1,000 users):

- Diarrhoea
- Flatulence
- Constipation
- Vomiting.

Very rare (may affect up to 1 in 10,000 users):

- Haematopoietic disorders, anaemia, leucopenia, thrombocytopenia, pancytopenia and agranulocytosis
- Serious hypersensitivity reactions, including facial, tongue and throat swelling, shortness of breath, fast heart beat, and low blood pressure
- Aseptic meningitis
- Peptic ulcer
- Gastrointestinal perforation or gastrointestinal haemorrhage
- Melaena (blood in the stool)

- Haematemesis (vomiting blood)
- Mouth ulceration and gastritis
- Exacerbation of colitis and Crohn's disease
- Liver disorder
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
- Acute renal failure
- Papillary necrosis, especially in long-term use, associated with increased serum urea and oedema
- Haemoglobin decreased.

Not known (frequency cannot be estimated from the available data):

- Cardiac failure and oedema
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- High blood pressure
- Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea
- Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome). DRESS symptoms include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalized exanthematous pustulosis). Stop giving Fasdol to your child if he / she develops these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light.

Exacerbation of infections related inflammation has been described. In exceptional cases, serious infections of the skin and soft tissues have occurred during chicken pox (varicella).

Other side effects include: dizziness, nervousness, depression, drowsiness, insomnia, vertigo, hearing disturbances such as tinnitus, haematuria, alveolitis, pulmonary eosinophilia, pancreatitis, visual disturbances.

High doses of ibuprofen (2.4 g daily) are associated with an increased risk of thrombotic events.

If your child gets these side effects or any side effects not listed in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE FASDOL

Keep this medicine out of the sight and reach of children!

Do not use Fasdol after the expiry date which is stated on the package.

Do not store above 25°C! Keep in the original package.

6. OTHER INFORMATION

What Fasdol 100 mg / 5 ml oral suspension contains:

The active substance is ibuprofen.

5 ml of oral suspension contain 100 mg ibuprofen.

The excipients are: glycerol, polysorbate, sucrose, sorbitol, microcrystalline cellulose and sodium carboxymethyl cellulose, saccharin sodium, citric acid monohydrate, sodium citrate dihydrate, sodium chloride, methyl hydroxybenzoate, propyl hydroxybenzoate, ethanol, strawberry aroma, and purified water.

Contents of the pack:

Carton box with one glass bottle of 150 ml and a graduated oral syringe.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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