

## **PACKAGE LEAFLET: Information for the patient**

### **FASDOL**

Suppositories – 75 mg, 150 mg

(Ibuprofen)

**Read all of this leaflet carefully before you start using this medicine 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 you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get 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 use Fasdol
3. How to use 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 antiinflammatory, analgesic and antipyretic properties. Fasdol is used in:

- mild to moderate pain;
- temperature;
- pain and inflammation of soft-tissue injuries;
- pain and inflammation in rheumatic disease including juvenile idiopathic arthritis;
- post-immunisation pyrexia in children.

Your doctor may have given Fasdol for another purpose. Ask your doctor if you want to know why you were given this drug.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU USE FASDOL**

### **Do not use Fasdol if you:**

- are allergic to ibuprofen or any of the excipients of Fasdol;
- have a history of asthma attack, angioedema, urticaria and rhinitis after taking aspirin or any other non-steroidal anti-inflammatory drug;
- have a history of gastrointestinal bleeding or perforation linked to prior therapy with nonsteroidal antiinflammatory drugs;
- have had previous or have active peptic ulceration or bleeding, which is repeated, (at least two episodes of detected ulcers or bleeding);
- suffer from brain bleeding (cerebrovascular bleeding) or other active bleeding;
- suffer from severe hepatic, renal or heart failure;
- are in the last trimester of pregnancy (see Pregnancy section).

Do not use Fasdol 75 mg suppositories in children weighing less than 7.5 kg (8 months).

Do not use Fasdol 150 mg suppositories in children weighing less than 15 kg (3 years old).

### **Take special care with Fasdol**

Ask your doctor or pharmacist before you use Fasdol.

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

Ibuprofen (2.4 g daily) is associated with an increased risk of thrombotic events.

Nonsteroidal antiinflammatory 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 antiinflammatory 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.

Serious skin reactions have been reported in association with ibuprofen treatment. You should stop using Fasdol and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Fasdol use should be avoided during a chickenpox infection.

In patients with cardiac impairment, caution is required since nonsteroidal antiinflammatory drugs may impair renal function.

Nonsteroidal antiinflammatory 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.

It is preferable to avoid nonsteroidal antiinflammatory drugs in patients with active or previous gastrointestinal ulceration or bleeding, and to withdraw them if gastrointestinal lesions develop, nevertheless patients with serious rheumatic diseases (e.g. rheumatoid arthritis) are usually dependent on nonsteroidal antiinflammatory drugs. For this reason, patients at risk of gastrointestinal ulceration (including elderly), who need treatment with nonsteroidal antiinflammatory drugs, should receive gastro-protective treatment.

The combination of nonsteroidal antiinflammatory drugs and low-dose aspirin can increase the risk of gastrointestinal side effects. For this reason, this combination should be used only if absolutely necessary and the patient should be monitored closely.

Special medical monitoring is needed if the patient has just gone through a major surgical intervention.

Talk to your pharmacist or doctor if you have an infection because 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 you use this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

### **Taking other medicines**

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

It is particularly important to inform your doctor that you are taking:

- **ACE inhibitors**, increased risk of renal impairment and antagonized hypotensive effect;
- **analgesics**, increased side effects from concomitant use of nonsteroidal antiinflammatory drugs with other nonsteroidal antiinflammatory drugs or aspirin; ibuprofen possibly reduces antiplatelet effect of aspirin;
- **anticoagulants**, enhanced anticoagulant effect of coumarins (warfarin) and phenindione and increased risk of bleeding when given with 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**, plasma concentration of ibuprofen increased by voriconazole;
- **antivirals**, increased risk of haematological toxicity when given with zidovudine;
- **beta-blockers and calcium-channel blockers**, their hypotensive effect is antagonised;
- **cytotoxics**, non-steroidal anti-inflammatory drugs probably reduce excretion of methotrexate increasing the risk of toxicity;
- **diuretics**, increased risk of nephrotoxicity of nonsteroidal antiinflammatory drugs and antagonized diuretic effect by nonsteroidal antiinflammatory drugs;
- **cardiac glycosides**, possibly increased plasma concentration of cardiac glycosides, (possible exacerbation of heart failure and reduction of renal function);
- **clopidogrel**, increased risk of bleeding;
- **corticosteroids**, increased risk of gastrointestinal bleeding and ulceration;

- **lithium**, nonsteroidal antiinflammatory drugs reduce excretion of lithium, increasing the risk of toxicity;
- **muscle relaxants**, ibuprofen reduces excretion of baclofen (increased risk of toxicity);
- **tacrolimus**, possible increased risk of nephrotoxicity when ibuprofen given with tacrolimus;
- **ciclosporin**, there may be a risk of kidney damage;
- **phenytoin**, the effect of phenytoin may be potentiated;
- **probenecid / sulfinpyrazone**, may delay the excretion of ibuprofen;
- **quinolone antibiotics**, convulsions may occur due to ibuprofen and quinolones interactions;
- **bisphosphonates**, nonsteroidal antiinflammatory drugs are predicted to increase the risk of gastrointestinal irritation and renal impairment when given with bisphosphonates.

### **Taking Fasdol with food and drinks**

It is not recommended to consume alcohol while you are using Fasdol.

### **Pregnancy, breastfeeding and fertility**

#### Pregnancy

It is advised to avoid use of nonsteroidal antiinflammatory drugs during the first and second trimester of pregnancy, unless the potential benefit outweighs the risk to the fetus. The use of nonsteroidal antiinflammatory drugs is contraindicated during the third trimester of pregnancy because it is associated with a risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn. In addition, the onset of labour may be delayed and its duration may be increased.

#### Breastfeeding

Even though ibuprofen and its metabolites are excreted in human breast milk only in very small amounts, it should not be administered during breastfeeding.

#### Fertility

Long-term use of some nonsteroidal antiinflammatory drugs is associated with reduced female fertility, which is reversible on stopping treatment.

Ask for your pharmacist's or doctor's advice before using this medicine.

### **Driving and using machines**

Ibuprofen given in high doses may cause central nervous system-related side effects such as fatigue and dizziness, so the patient's reaction can be modified and his ability to drive a car or operate machinery can be impaired. This is especially true when alcoholic beverages are taken simultaneously.

### **3. HOW TO USE FASDOL**

Always use this medicine 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.

Do not use Fasdol for more than four days without consulting a doctor or dentist.

Unless otherwise prescribed by the doctor, the usual dosage is:

<b>Age</b>	<b>Weight</b>	<b>Single dose</b>	<b>Maximum daily dose</b>
8 – 12 months	7.5 – 9 kg	1 suppository (75 mg)	3 suppositories (225 mg / day)
1 – 2 years	10 – 12 kg	1 suppository (75 mg)	4 suppositories (300 mg / day)
3 – 5 years	15 – 19 kg	1 suppository (150 mg)	3 suppositories (450 mg / day)
6 – 9 years	20 – 29 kg	1 suppository (150 mg)	4 suppositories (600 mg / day)

The dosage interval depends on the symptoms and the maximum daily dose and should be at least six hours. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Fasdol is for rectal use only. The suppository should be used after defecation (with empty rectum) and placed deep into the rectum.

### **If you use more Fasdol than you should**

If you use more Fasdol than you should, or if the children take it accidentally, 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 are unlikely to cause toxicity in children.

### **If you forget to use Fasdol**

If you forget to use one dose (or more than one dose), use the next dose in its usual time.

Do not use a double dose (or higher) to make up 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. The possible side effects of Fasdol are:

### Effects on the cardiovascular system

Ibuprofen can increase blood pressure. The recent use of non-steroidal anti-inflammatory drugs has been associated with an increased risk of developing heart failure in elderly patients. Clinical study data suggest that high-dose ibuprofen (2.4 g daily) is associated with an increased risk of thrombotic events.

It has been suggested that nonsteroidal antiinflammatory drugs may reduce the cardioprotective effect of aspirin.

### Effects on the blood

Blood disorders including agranulocytosis, aplastic anaemia, pure white-cell aplasia, and thrombocytopenia have been reported in patients taking ibuprofen.

### Effects on the CNS and psychiatric disorders

Headache, dizziness, agitation, irritability, fatigue, hearing loss, and tinnitus are the most frequent CNS adverse effects in patients taking non-steroidal anti-inflammatory drugs. Aseptic meningitis has occurred in patients with systemic lupus erythematosus who were receiving ibuprofen. Psychiatric effects include psychotic reactions and depression, which are very rare.

### Effects on the eyes

Reversible amblyopia has been reported in patients receiving ibuprofen, while ocular effects such as blurred vision occur rarely.

### Effects on the gastrointestinal tract

Ibuprofen may be associated with a lower risk of upper gastrointestinal effects than some other non-steroidal anti-inflammatory drugs, but nonetheless it can cause abdominal pain, nausea, dyspepsia, vomiting, flatulence, diarrhea, constipation, gastrointestinal bleeding, oral mucosa inflammation (ulcerative stomatitis), peptic ulcers and perforation. Colitis and its exacerbation have been reported from treatment with ibuprofen. Inflammation of the pancreas (pancreatitis) is very rarely reported.

### Effects on the kidneys

Reports of adverse renal effects with ibuprofen include an increase in serum creatinine concentration, decrease in urinary excretion and increased water retention (edema), acute renal failure, and nephrotic syndrome. Cystitis, haematuria, interstitial nephritis, and papillary necrosis may occur.

### Effects on electrolytes

Hyponatraemia has been described in patients receiving ibuprofen.

### Effects on the skin

Skin rashes may occur during hypersensitivity reactions although serious dermatological effects attributed to ibuprofen are rare. Reports of more serious effects have included Stevens-Johnson syndrome (often associated with hepatotoxicity), toxic epidermal necrolysis (*Lyell* syndrome), hair loss, photosensitivity, and bullous leukocytoclastic vasculitis.

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 generalised exanthematous pustulosis) may occur. Stop using Fasdol if you develop these symptoms and seek medical attention immediately. See also section 2.



There may be an increased risk of severe skin and soft tissue complications associated with the use of nonsteroidal antiinflammatory drugs, mostly in patients with chickenpox.

#### Effects on immune system

Hypersensitivity reactions may occur occasionally and include fever, angioedema, bronchospasm as well as asthma attacks (possibly with a drop in blood pressure), and rashes. Facial edema, tongue swelling, internal laryngeal swelling with constriction of the airways, shortness of breath, palpitations, drop in blood pressure and life-threatening shock are very rarely reported. In these cases, immediate medical attention is required.

#### Effects on the liver

Raised liver transaminase values were noted in 3 patients with chronic hepatitis C infection after taking ibuprofen, which returned to normal on stopping the drug. Other hepatic adverse effects reported with ibuprofen include hepatitis and liver failure.

If you get 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 contains:**

**The active substance** is ibuprofen.

Each suppository contains 75 mg or 150 mg ibuprofen.

**The excipients** are: colloidal anhydrous silica, diethyleneglycol monoethylether and hard fat.

#### **Contents of the pack:**

Carton box with 10 suppositories (75 mg or 150 mg).

**Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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