PACKAGE LEAFLET:
Information for the user

FASDOL

Film-coated tablets – 400 mg, 600 mg
(Ibuprofen)

Read this leaflet carefully before you start taking this medicine.
- 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 personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please talk to your doctor or pharmacist.

In this leaflet:

1. WHAT FASDOL IS AND WHAT IT IS USED FOR?

Fasdol contains ibuprofen, which is a non - steroidal anti-inflammatory, antipyretic and analgesic (antiphlogistic / antirheumatic) drug (NSAID).

Fasdol is indicated in (only for the tablet 400 mg):
- mild to moderate pain
- fever.

Fasdol is used:
for the symptomatic treatment of pain and inflammation in:
- acute arthritis (including gout)
- chronic arthritis, particularly rheumatoid arthritis (chronic polyarthritis)
- ankylosing spondylitis (Bechterew's disease) and other inflammatory rheumatic diseases of the spine
- irritation of degenerative joint and spine diseases (arthritis and spondylarthritis)
- soft tissue inflammatory rheumatic diseases
- painful swelling and inflammation after injury.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FASDOL?

Do not take Fasdol:
- if you are hypersensitive (allergic) to ibuprofen or any of the other excipients of Fasdol
- if you have had reactions of asthma attacks, rhinitis or urticaria after taking aspirin or other nonsteroidal anti-inflammatory drugs in the past
- if you have unexplained blood formation disorders
- if you have existing or a history of repeated peptic or duodenal ulceration or haemorrhage (at least 2 distinct episodes of proven ulceration or bleeding)
- if you have had gastrointestinal bleeding or perforation in history related to therapy with anti-inflammatory drugs (NSAIDs)
- if you have brain hemorrhage (cerebrovascular bleeding) or other active bleedings
- in severe hepatic or renal dysfunction
- in severe heart failure
- in the last trimester of pregnancy
- if you are a child or adolescent under 15 years.

The following describes the cases when Fasdol should be used only under certain conditions (i.e., at longer intervals or at a reduced dose and under medical supervision) and with special caution. Consult with your doctor. This applies even if you have had these conditions in the past.

Take special care with Fasdol
Gastrointestinal safety
The concomitant use of Fasdol in combination with other non – steroidal antiinflammatory drugs, including selective COX-2 inhibitors (cyclooxygenase inhibitors), should be avoided.
Side effects can be reduced by using the lowest effective dose for the shortest duration necessary to control the symptoms.

Elderly:
In elderly patients, during therapy with non – steroidal anti-inflammatory drugs, it comes to more adverse effects, especially gastrointestinal bleeding and perforation which in specific circumstances may be life – threatening. Therefore, a careful medical control is necessary in the elderly.

Gastrointestinal bleeding, ulcers and perforations:
Gastrointestinal bleeding, ulcers or perforations which may be fatal, have been reported with all NSAIDs. They have occurred with or without warning symptoms or serious gastrointestinal events in the anamnese at any time during therapy.

The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 2: “Do not take Fasdol”), and in elderly patients. These patients should commence the treatment with the lowest available dose. For these patients and for patients who require concomitant treatment with low-dose acetylsalicylic acid or other drugs likely to increase gastrointestinal risk, a combination therapy with gastric protective agents (e.g. misoprostol or proton pump inhibitors) should be considered eligible.
If you have a history of gastrointestinal adverse effects, particularly if you are in older age, you should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment.
Caution is advised if you receive concomitantly medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors which among others are used to treat depressive disorders, or platelet aggregation inhibitors such as acetylsalicylic acid (see section 2: “Taking Fasdol with other medicines”).
When it comes to gastrointestinal bleeding or ulcers while taking Fasdol, the treatment should be discontinued.

NSAIDs should be used with caution in patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated (see section 4: “Possible side effects”).

Cardiovascular effects
Medicines like Fasdol may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment!
If you have heart problems, previous stroke or think you might be at risk for these conditions (e.g. if you have high blood pressure, diabetes or high cholesterol, or are a smoker), you should discuss your treatment with your doctor or pharmacist.

Skin reactions
Severe skin reactions, with redness and blistering, some fatal (exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis / Lyell's syndrome; see section 4: “Possible side effects”) have been reported very rarely with NSAID therapy. The highest risk for these reactions appears to be at the beginning of therapy, the reactions occurring in the majority of cases within the first month of treatment. At the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity reaction, Fasdol should be discontinued and a doctor should be consulted immediately.
In the presence of varicella infection, the use of Fasdol should be avoided.

Other recommendations
Fasdol should only be used under strict consideration of the benefit-risk ratio in:
- congenital disorder of blood count (e.g., acute intermittent porphyria)
- some autoimmune diseases (systemic lupus erythematosus and mixed collagenosis).

A particularly careful medical supervision is required:
- immediately after major surgery
- in allergy (e.g. skin reactions caused by other drugs, asthma, hay fever), chronic swelling of the nasal mucosa or obstructive airways disease
- in impaired renal or hepatic function.

Severe acute hypersensitivity reactions (e.g. anaphylactic shock) are very rare. At the first signs of a hypersensitivity reaction after ingestion of Fasdol, the treatment must be stopped. According to the symptoms, the necessary medical measures must be taken by competent persons.

Ibuprofen, the active ingredient of Fasdol, may temporarily inhibit platelet function (platelet aggregation). Therefore, patients with coagulation disorders should be carefully monitored.

During long-term administration of Fasdol, periodic monitoring of liver function, renal function and blood counts is required.

If Fasdol is taken before surgical procedures, the doctor or dentist should be consulted or informed.

During long-term use of analgesics, headaches can occur, which should not be treated with increasing doses of the drug. Consult with your doctor if you experience headache frequently despite treatment with Fasdol!

In general, the habitual intake of analgesics, especially when different analgesic drugs are combined, can lead to permanent kidney damage with the risk of renal failure (analgesic nephropathy).

Regarding fertility, see section “Fertility”.

Children and adolescents
Children and adolescents under 15 years should not take Fasdol, since the active ingredient content is too high. For this age group different ibuprofen preparations are available with lower drug concentration.

Taking Fasdol with other medicines
Tell your doctor or pharmacist if you take / use or have recently taken / used other medicines, including those taken without a prescription.
The concomitant use of Fasdol with digoxin (used to increase the myocardial contractility), phenytoin (to treat convulsions) or lithium (to treat mental – emotional disorders), may increase the blood levels of these drugs. Monitoring of serum lithium levels is necessary. Monitoring of serum digoxin and serum phenytoin levels is recommended.

Anticoagulants (e.g., acetylsalicylic acid / aspirin, warfarin, ticlopidine), medicines for high blood pressure (ACE inhibitors such as captopril, beta-blockers, angiotensin II receptor antagonists) and some other medicines may affect treatment with ibuprofen or be affected. Therefore, you should always seek medical advice before using ibuprofen at the same time as other medicines.

Fasdol may reduce the effect of diuretics and antihypertensives.

Fasdol may reduce the effect of ACE-inhibitors (medicines for treatment of heart failure and hypertension). By concomitant use, the risk of occurring of renal function damage may increase further.

The concomitant administration of Fasdol and potassium – sparing diuretics can lead to increased blood potassium levels.

Co-administration of Fasdol with other antiinflammators and analgesics of NSAIDs or with glucocorticoids, may increase the risk of gastrointestinal adverse effects.

Antiplatelet agents (such as aspirin) and some antidepressants (selective serotonin reuptake inhibitors / SSRI) may increase the risk of gastrointestinal bleeding.

The use of Fasdol within 24 hours before or after administration of methotrexate can lead to an increased concentration of methotrexate and increase its toxic effect.

The risk of nephrotoxic effect of cyclosporin (to prevent rejection after the transplant, but also used to treat rheumatic disorders), is increased by concomitant administration of certain non-steroidal anti-inflammatory drugs. This effect can not be ruled out for the combination of cyclosporine with ibuprofen.

Medicines containing probenecid or sulfinpyrazone (medicines to treat gout), may delay the excretion of ibuprofen. Thus, the quantity of Fasdol in the body may increase potentiating the adverse effects.

NSAIDs may increase the effect of anticoagulants, e.g. warfarin. During co – administration, the coagulation should be checked.

Clinical studies have shown interactions between non-steroidal anti-inflammatory drugs (NSAIDs) and sulfonylureas (medicines to lower blood sugar levels). Although interactions between ibuprofen and sulfonylureas have not been described, control of blood glucose levels is recommended while taking these drugs concomitantly.

Tacrolimus: the risk of nephrotoxicity is increased when both drugs are administered simultaneously.

Zidovudin: there is evidence of an increased risk of hemorrhage in the joints (haemarthrosis) and haematomas in HIV-positive haemophilic patients taking zidovudine and ibuprofen at the same time.

Taking Fasdol with food and drinks
You should not drink alcohol while you are taking Fasdol.

Pregnancy and lactation
Ask your doctor or pharmacist for advice before taking / using any medicine.

Pregnancy
If a pregnancy occurs during the use of Fasdol, the doctor must be informed. Ibuprofen may be used in the first and second trimester of pregnancy only after consultation with your doctor. In the last trimester of pregnancy Fasdol should not be administered because of an increased risk of complications for the mother and the child.

Lactation
The active ingredient ibuprofen and its metabolites are excreted in breast milk in small amounts. Since adverse effects on the infant are not known so far, during short-term use, an interruption of breastfeeding is usually not required. If a longer use or with higher doses is prescribed, an early weaning should be considered.

Fertility
The intake of Fasdol, like the use of other drugs known to inhibit prostaglandin synthesis, may make it difficult to get pregnant. You should inform your doctor if you plan a pregnancy or if you have problems getting pregnant.

Driving and using machines
Since the use of Fasdol at higher doses can cause CNS side effects such as fatigue and dizziness and may in some cases change the responsiveness, the ability to drive and to use machines may be affected. This applies even more in combination with alcohol. You can not respond quickly and effectively enough to unexpected and sudden events. In such case do not drive a car or other vehicles! Do not use any tools or machines! Do not work without a secure fit!

3. HOW TO TAKE FASDOL?

Always take Fasdol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, the usual dose is:
For pain relief and fever:

Age	Single dose Fasdol – 400 mg	Total daily dose: Fasdol – 400 mg
Adolescents over 15 years and adults	1 film-coated tablet (equivalent to 400 mg ibuprofen)	2 - 3 film - coated tablets (equivalent to 800 -1200 mg ibuprofen)

For the treatment of rheumatic diseases:
Ibuprofen, the active substance of Fasdol is dosed depending on the age and body weight.
The recommended dose for adults and adolescents from 15 years is between 1200 and 2400 mg ibuprofen daily. The maximum single dose for adults should not exceed 800 mg ibuprofen.

Age	Single dose: Fasdol – 400 mg	Total daily dose: Fasdol – 400 mg
Adolescents over 15 years and adults	1 2 film-coated tablets (equivalent to 400 - 800 mg ibuprofen)	3 - 6 film - coated tablets (equivalent to1200-2400 ibuprofen)

Age	Single dose: Fasdol – 600 mg	Total daily dose: Fasdol – 600 mg
Adolescents over 15 years and adults	½ - 1film-coated tablets (equivalent to 300 - 600 mg ibuprofen)	2 - 4 film - coated tablets (equivalent to1200-2400 ibuprofen)

Method and duration of use
Take Fasdol whole, with plenty of fluid and not on an empty stomach. If you have a sensitive stomach, it is advisable to take Fasdol during the meals.
In mild to moderate pain and in fever, do not take Fasdol longer than 4 days without consulting a doctor or a dentist.
In rheumatic diseases, the use of Fasdol may be required for a longer period. Your doctor will decide for the duration of treatment.

If you take more Fasdol than you should
Take Fasdol as your doctor has told you or according the dosage recommendations of the leaflet. If you have the impression that you don’t have alleviation of the pain, do not increase the dose by yourself, but consult with your doctor.

The symptoms of an overdose may be: CNS disorders such as headaches, dizziness, drowsiness and unconsciousness (and myoclonic seizures in children) as well as abdominal pain, nausea and vomiting. Furthermore, gastrointestinal bleeding and functional disorders of liver and kidney are possible. Further, there may be hypotension, respiratory depression and bluish coloring of the skin and mucosa (cyanosis).

There is no specific antidote.

If you suspect for an overdose with Fasdol, contact your doctor. He will decide for the necessary measures depending on the gravity of the intoxication.

If you forget to take Fasdol
If you forget to take the medicine once, do not take more than usual in the next dose.
If you have other questions on the use of this medicine, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ibuprofen can cause side effects, although not everybody gets them.
The frequency of possible side effects is evaluated as listed below:

Very common	may affect more than 1 in 10 people
Common	may affect 1 to 10 people from 100
Uncommon	may affect 1 to 10 people from 1.000
Rare	may affect 1 to 10 people from 10.000
Very rare	may affect 1 person from 10.000
Not known	Frequency cannot be estimated from the available data.

Possible side effects
The following adverse drug reactions must be taken into account that they are mainly dose-dependent and inter-individually different.

The most commonly observed adverse events are gastrointestinal Gastroduodenal ulcers (peptic ulcers), perforation or bleeding, sometimes fatal, can occur, especially in elderly patients (see section 2: “Take special care with Fasdol”).
Nausea, vomiting, diarrhea, bloating, constipation, indigestion, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease (see section 2: “Take special care with Fasdol”) have been reported after use. Gastritis has been observed less frequently. In particular, the risk for the occurrence of gastric intestinal bleeding depends on the range of doses and the duration of use.

Edema, hypertension and heart failure have been reported in association with NSAID treatment.

Medicines like Fasdol may be associated with a small increased risk of cardiac attacks (myocardial infarction) or stroke.

Cardiac disorders
Very rare: palpitations, edema (fluid retention), heart failure, heart failure, myocardial infarction.

Blood and lymphatic system disorders
Very rare: blood formation disorders (anemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis).
The first signs may include: fever, sore throat, superficial wounds in the mouth, flu-like symptoms, severe fatigue, nosebleeds and bruising.
In such case, the drug should be discontinued immediately and the doctor should be informed. Any self – medication for pain relief or fever should be avoided.
In case of long-term therapy blood counts should be monitored regularly.

Nervous system disorders
Common: central nervous system disorders such as: headache, dizziness, insomnia, agitation, irritability or fatigue.

Eye disorders
Uncommon: blurred vision.

Ear and labirynth disorders
Very rare: tinnitus, hearing disturbances.

Gastrointestinal tract disorders
Very common: gastrointestinal symptoms such as heartburn, abdominal pain, nausea, vomiting, bloating, diarrhea, constipation and minor gastrointestinal blood loss, which can cause anemia in exceptional cases.
Common: gastrointestinal ulcers (peptic ulcers), possibly with bleeding and perforation. Ulcerative stomatitis, exacerbation of colitis and Crohn's disease.
Uncommon: inflammation of the gastric mucosa (gastritis).
Very rare: inflammation of the esophagus (esophagitis), pancreatitis, formation of membranes in the intestine and colon (diaphragm-strictures).
If you experience severe pain in the upper abdomen, hematemesis, melena and / or dark – colored stools, you should discontinue Fasdol and seek immediate medical attention.

Renal and urinary tract disorders
Uncommon: formation of edema due to excessive fluid retention in the tissues, especially in patients with arterial hypertension or renal damage; nephrotic syndrome (water retention in the body [edema] and high excretion of proteins in urine); inflammatory disease of the kidneys (interstitial nephritis), which may be associated with acute renal disorders.
Very rare: kidney tissue damage (papillary necrosis) and elevated uric acid levels in the blood.
Reduction in urinary excretion, accumulation of water in the body (edema) and general discomfort can be an expression of kidney disease and even renal failure.
If you experience the above mentioned symptoms or their exacerbation, you should stop taking Fasdol and immediately contact your doctor.

Skin and subcutaneous tissue disorders
Very rare: severe skin reactions, such as: bullous rash (e.g. Stevens - Johnson syndrome, toxic epidermal necrolysis / Lyell's syndrome), hair loss (alopecia).
In exceptional cases there may be an occurrence of serious skin infections and soft tissue complications of varicella infection (see also "Infections and infestations").

Infections and infestations
Very rare: a deterioration of the inflammation caused by infection (e.g. development of necrotizing fasciitis) has been described in temporal association with the use of some anti - inflammatory drugs (non – steroidal antiinflammatories; these also include Fasdol).
If during the use of Fasdol occur signs of a new infection (e.g. redness, swelling, excessive heat, pain, fever) or worsen, the doctor should be consulted immediately.

Very rare:the symptoms of a brain inflammation not caused by an infection (aseptic meningitis), such as: severe headache, nausea, vomiting, fever, neck stiffness or clouding of consciousness were observed with the use of ibuprofen. Patients with autoimmune diseases (systemic lupus erythematosus, mixed colagenosis) seem to be predisposed.

Vascular disorders
Very rare: high blood pressure (arterial hypertonia).

Immune system disorders
Uncommon: hypersensitivity reactions with skin rashes and itching, as well as asthma attacks (possibly with drop of blood pressure).
In this case, the doctor should be informed immediately and Fasdol should no longer be used.

Very rare: severe systemic hypersensitivity reactions. They can be manifested as: facial edema, tongue swelling, internal laryngeal swelling with narrowing of the airways, shortness of breath, tachycardia, drop in blood pressure leading to life-threatening shock.

When one of those phenomena occurs, which may even be at first use, immediate medical attention is required.
Inform your doctor immediately and do not take Fasdol anymore.

Hepatobiliary disorders
Very rare: liver dysfunction, liver damage, especially during long-term therapy, liver failure, acute inflammation of the liver (hepatitis).
During long-term use, the liver function tests should be monitored regularly.

Psychiatric disorders
Very rare: psychotic reactions, depression.

Inform your doctor or pharmacist if you get any side effects or if you notice side effects not listed in this leaflet.

5. HOW TO STORE FASDOL?

Keep this medicine out of the sight and reach of children.
Store below 25°C.
Do not use this medicine after the expiry date which is stated on the blister and carton box after “Skad“.
The expiry date refers to the last day of that month.

6. OTHER INFORMATIONS

What Fasdol – film-coated tablet 400 mg contains
The active substance is ibuprofen.
1 film-coated tablet contains 400 mg ibuprofen, ½ film-coated tablet contains 200 mg ibuprofen.

The other excipients are:
maize starch, sodium starch glycolate (type A), hypromellose, talc, colloidal anhydrous silica, magnesium stearate, titanium dioxide (E 171), macrogol 6000.

What Fasdol – film-coated tablet 600 mg contains
The active substance is ibuprofen.
1 film-coated tablet contains 600 mg ibuprofen, ½ film-coated tablet contains 300 mg ibuprofen.

The other excipients are:
maize starch, croscarmellose sodium, hypromellose, talc, colloidal anhydrous silica, magnesium stearate, titanium dioxide (E 171), macrogol 6000.

What Fasdol looks like and contents of the pack
Fasdol are white film-coated tablets, oblong, with a score – line on both sides.

Content of the pack
Box with 10 film-coated tablets.
Box with 20 film-coated tablets.

Explanatory of the illustration icons on the packaging:

Without medical prescription.

According medical prescription.

Be careful during pregnancy.

Should not be taken by children.

+15 The age that this medicine can be used is over 15 years old.

Content. Warning. Tablet shape.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel./Fax: 00355 4 23 62 800
Tirana - ALBANIA

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SPECIFICATION CROPING AREA 15 x 42.5

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