PACKAGE LEAFLET: Information for the patient

DOLOMED

Solution for injection – 160 mg / 2 ml

(Ketoprofen lysine)

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 only. Do not pass it on to others. It may harm them, even if their signs of illnes 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 tell your doctor or pharmacist.

In this leaflet

1. WHAT DOLOMED IS AND WHAT IT IS USED FOR

Dolomed contains the active substance ketoprofen lysine.

Ketoprofen, a propionic acid derivative, is a nonsteroidal anti-inflammatory drug (NSAID).

Dolomed is indicated in:

- the treatment of acute exacerbations of musculoskeletal, joint, articular, peri-articular and soft tissue disorders;
- the management of pain after orthopaedic surgery.

Your doctor may have given you Dolomed for another reason. Ask your doctor if you want to know why you are taking Dolomed.

2. BEFORE YOU TAKE DOLOMED

Do not take Dolomed if:

- you have a known hypersensitivity (allergy) to ketoprofen, sodium metabisulfite or any other ingredient of the product;
- you have ever had asthma attack, angioedema, urticaria or rhinitis after taking aspirin or any other NSAID;
- you have had previous or have an active peptic ulceration;
- you suffer from severe hepatic, renal or heart failure;
- you have a history of bronchial asthma;
- you are during the third trimester of pregnancy (see section Pregnancy, Breastfeeding and Fertility).

Take special care with Dolomed

Ask your doctor before taking Dolomed.

Talk to your pharmacist or doctor if you have an infection - please see heading “Infections” below.

Special attention should be given to patients with renal impairment. Renal function should regularly be monitored as sodium and water retention may occur which may deteriorate renal function, possibly leading to renal failure.

Caution is required also in patients with hepatic impairment since there is an increased risk of gastro-intestinal bleeding and fluid retention.

Dolomed should also be used with caution in the elderly (there is an increased risk of serious undesirable effects and fatalities), in patients with allergic disorders, problems with blood coagulation, connective tissue disorders and cardiac impairment.
It is preferable to avoid nonsteroidal anti-inflammatory drugs (including ketoprofen) in patients with active or previous gastro-intestinal ulceration or bleeding, and to withdraw them if gastro-intestinal lesions develop.

Nevertheless, patients with serious rheumatic diseases (e.g. rheumatoid arthritis) are usually dependent on nonsteroidal anti-inflammatory drugs. For this reason, it is recommended that patients who need nonsteroidal anti - inflammatory drugs treatment and have a risk of gastro-intestinal ulceration (including the elderly), should receive gastroprotective treatment.

Concomitant use of a nonsteroidal anti-inflammatory drug and low-dose aspirin can increase the risk of gastro-intestinal effects. For this reason, this combination should be used only if it is absolutely necessary, and the patient should be closely monitored.

Infections

Dolomed may hide signs of infections such as fever and pain. It is therefore possible that Dolomed 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 take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Taking other medicines

Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.
The following interactions (except probenecid) apply to NSAIDs in general.

Inform your doctor if you are taking / using the following medicines:

- *other nonsteroidal anti-inflammatory drugs:* increased risk of gastro-intestinal damage (this combination should be avoided);
- *quinolones*: increased risk of convulsions;
- *anticoagulants*: enhanced anticoagulant effect of coumarins and phenindione; increased risk of bleeding if nonsteroidal anti - inflammatory drugs are given with dabigatran etexilate or heparins;
- *selective serotonin re-uptake inhibitors (SSRIs) and venlafaxine*: increased risk of bleeding;
- *antidiabetics*: enhanced effects of sulfonylureas;

- *antivirals*: increased plasma concentration of nonsteroidal anti - inflammatory drugs by ritonavir and increased risk of haematological toxicity when nonsteroidal anti - inflammatory drugs are given with zidovudine;
- *ciclosporin*: increased risk of nephrotoxicity;
- *cytotoxics*: possible reduction of excretion of methotrexate (increased risk of toxicity);
- *diuretics*: increased risk of nephrotoxicity and antagonism of the diuretic effect;
- *lithium*: reduced excretion of lithium;
- *pentoxiphylline*: increased risk of bleeding;
- *probenecid:* reduced excretion of ketoprofen (increased plasma concentration);
- *tacrolimus:* increased risk of nephrotoxicity.

Taking Dolomed with food and drinks

Not applicable.

Pregnancy

It is recommended to avoid using nonsteroidal anti-inflammatory drugs during the first and the second trimester of pregnancy, except when the potential benefit for the mother outweighs the potential risk to whom the fetus is exposed.

Nonsteroidal anti-inflammatory drugs are contraindicated during the last trimester of pregnancy because their use 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 prolonged.

Breastfeeding

It is not recommended during breastfeeding.

Fertility

Long-term use of some nonsteroidal anti-inflammatory drugs might reduce female fertility. This effect is reversible on stopping treatment.

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

Driving and using machines

Since ketoprofen may cause dizziness, drowsiness, vertigo and visual disturbances, caution should be paid when driving or using machines.

Important information for some of the ingredients of Dolomed

Dolomed contains sodium metabisulfite. Sodium metabisulfite may rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW TO TAKE DOLOMED

Always take Dolomed exactly as your doctor has told you. If you are not sure, contact your doctor or pharmacist.

The recommended dose is 50 – 100 mg ketoprofen (equivalent with 80 – 160 mg ketoprofen lysine) every 4 hours, up to the maximum dose of 200 mg ketoprofen (equivalent with 320 mg ketoprofen lysine) in 24 hours. The treatment can last up to 3 days.

Dolomed is not recommended for children.

In patients with renal impairment, the lowest effective dose should be used for the shortest possible duration.

Dolomed is given by deep intramuscular injection (into the gluteal muscle).

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).

If you take more Dolomed than you should

If you take more Dolomed than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital, or call the emergency to get an opinion on the risk and advice on the actions that should be taken.

If you forget to take Dolomed

If you forget to take one dose (or more than one dose), take the next dose in its usual time.
Do not take a double dose (or higher) to make up for a forgotten dose.
If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dolomed can cause side effects, although not everybody gets them.
Nonsteroidal anti-inflammatory drugs can cause:

- *gastro-intestinal disturbances* including discomfort, nausea, diarrhoea and occasionally, bleeding and ulceration may occur;
- *hypersensitivity reactions* particularly rashes, angioedema and bronchospasm may occur;
- *renal failure* (especially in patients with pre-existing renal impairment); rarely, papillary necrosis or interstitial fibrosis can lead to renal failure;
- *other symptoms (which occur less commonly*) include: headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, hearing disturbances such as tinnitus, photosensitivity and haematuria, blood disorders, fluid retention (rarely precipitating congestive heart failure), increase of blood pressure, hepatic damage, alveolitis, pulmonary eosinophilia, pancreatitis, visual disturbances, Stevens-Johnson syndrome, and toxic epidermal necrolysis.

Cases of colitis (or exacerbation of colitis), Crohn's disease and aseptic meningitis have also been rarely reported. Patients with connective-tissue disorders (such as systemic lupus erythematosus) are especially susceptible to these side effects.

When Dolomed is given intramuscularly, there may be pain at the injection site and occasionally tissue damage.

Tell your doctor or pharmacist if you experience these side effects or if you notice any other side effects not listed in this leaflet.

5. HOW TO STORE DOLOMED

Keep out of the reach and sight of children!

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

Do not store above 25°C.

Keep in the original package to protect from light.

6. OTHER INFORMATION

What Dolomed 160 mg / 2 ml solution for injection contains

The active substance is ketoprofen lysine.

1 ampoule 2 ml contains 160 mg of ketoprofen lysine equivalent with 100 mg ketoprofen.

The other ingredients are: sodium metabisulfite, trisodium citrate, sodium hydroxide, water for injection.

Content of the pack

Carton box with 10 ampoules of 2 ml

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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