PACKAGE LEAFLET:
Information for the user

# DOLOMED

Solution for injection – 160 mg / 2 ml
*(Ketoprofen lysine)*

**Read all of 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. 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 becomes worse 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 as active substance ketoprofen lysine.
Ketoprofen (as lysine) is a nonsteroidal antiinflammatory drug (NSAID).
Dolomed is indicated in:
- treatment of acute exacerbations of musculoskeletal, articular, peri-articular and soft tissue disorders;
- the management of pain after orthopaedic surgery.

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

## 2. BEFORE YOU TAKE DOLOMED

**Do not take Dolomed if you:**
- have hypersensitivity (allergy) to ketoprofen, sodium metabisulfite or any other component of the solution;
- have a history of asthma attack, angioedema, urticaria and rhinitis because of aspirin intake or any other NSAID;
- suffer or have suffered from peptic ulceration;
- have severe hepatic, renal or heart failure;
- suffer from or have a history of bronchial asthma;
- are in the third trimester of pregnancy (see "Pregnancy, breastfeeding and fertility" section).

**Take special care with Dolomed**
Ask your doctor before taking Dolomed.
Special caution should be applied in patients with renal impairment. Renal function should be monitored continously as sodium and water retention in organism may occur, which may deteriorate and possibly lead to renal function block.
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 allergy disorders, blood coagulation problems, connective tissue disorders and cardiac impairment.

NSAIDs (including ketoprofen) should be avoided in patients with active or previous gastro-intestinal ulceration or bleeding, and at the same time should be advised to withdraw from them if gastro-intestinal lesions develop.
Nevertheless patients with serious rheumatic diseases (e.g. rheumatoid arthritis) are usually dependent on NSAIDs. For this reason, patients at risk of gastro-intestinal ulceration (including the elderly), who need NSAID treatment should receive gastroprotective treatment.

Since the combination of a NSAID and low-dose aspirin can increase the risk of gastro-intestinal effects, this combination should be used only if absolutely necessary and the patient should be monitored closely.

**Taking other medicines**
Tell your doctor or pharmacist if you are taking or have taken recently other drugs, including those without prescription.
The following interactions (except probenecid) regard NSAIDs in general.
Tell your doctor especially if you are taking the following drugs:
- *other NSAIDs:* there is an 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 when NSAIDs are given with dabigatran etexilate or heparins;
- *selective serotonin re-uptake inhibitors and venlafaxine:* increased risk of bleeding;
- *antidiabetics:* enhanced effects of sulfonylureas;
- *antivirals:* increased plasma concentration of NSAIDs by ritonavir and increased risk of haematological toxicity when NSAIDs are given with zidovudine;
- *ciclosporin:* increased risk of nephrotoxicity;
- *cytotoxics:* 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;
- *pentoxyphylline:* 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, breastfeeding and fertility**
*Pregnancy*
NSAIDs should be avoided during the first and second trimester of pregnancy unless the potential benefit for the mother outweighs the potential risk to which the fetus is exposed.
NSAIDs are contraindicated during the last trimester of pregnancy because the use of NSAIDs 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*
Its use is not recommended during breastfeeding.

*Fertility*
Long-term use of some NSAIDs is associated with reduced female fertility, which is reversible on stopping treatment.

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

**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 about some of the ingredients of Dolomed**
Dolomed contains sodium metabisulphite which 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, talk to your doctor or pharmacist.

The recommended dose is 50 – 100 mg ketoprofen (corresponding to 80 - 160 mg ketoprofen lysine) every 4 hours, up to a maximum dose of 200 mg ketoprofen (corresponding to 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.
The solution is given by deep intramuscular injection into the gluteal muscle.

**If you take more Dolomed than you should**
If you take more Dolomed than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital, or call the emergency to get an opinion of the risk and advice on the actions to be taken.

**If you forget to take Dolomed**
If you forget a dose, take the next dose when it is the normal time to take it.
Do not take a double dose to make up for the 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, Dolomed also can cause side effects, although not everybody may get them.

Nonsteroidal antiinflammators may cause:
- *gastrointestinal disturbances* such as: discomfort, nausea, diarrhoea and occasionally, bleeding and ulceration;
- *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 (more rarely) such as: headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, hearing disturbances such as tinnitus, photosensitivity, haematuria, blood disorders, fluid retention (rarely precipitating heart failure may occur), increase of blood pressure, hepatic damage, alveolitis, pulmonary eosinophilia, pancreatitis, visual disturbances, Stevens - Johnson syndrome, and toxic epidermal necrolysis.

Induction or exacerbation of colitis or Crohn's disease and aseptic meningitis have been rarely reported. Patients with connective-tissue disorders such as systemic lupus erythematosus may be especially susceptible.

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

Inform your doctor or pharmacist if you experience any of these side effects or any other side effect not mentioned 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.
Store below 25°C.
Store in the original package to protect it from light.

## 6. FURTHER INFORMATION

**What Dolomed – solution for injection – 160 mg / 2 ml contains**
**The active substance** is ketoprofen lysine.
Each 2 ml ampoule contains 160 mg ketoprofen lysine equivalent to 100 mg ketoprofen.
**The other ingredients** are: sodium metabisulphite, trisodium citrate, sodium hydroxide, water for injection.

**Content of the pack**
Box with 10 ampoules 2 ml.
Box with 100 ampoules 2 ml (for hospital use).

**Explanatory of the illustration icons on the packaging:**

Ask your doctor or pharmacist.

Content.

Warning.

Solution for injection.

**Marketing Authorisation Holder and Manufacturer:**

**PROFARMA Sh.a.**
Rruga "Myslym Keta"
Tel.Fax: 00 355 4 23 62 800
Tirana - ALBANIA

**This leaflet was first formulated in February 2013.**

SPECIFICATION

CROPING AREA 12 x 19 cm

**PAY ATENTION**, all the layers are visible.
If you have to print this document please check or uncheck the specific layers.