PACKAGE LEAFLET: Information for the user

KETROMINE

Solution for injection – 30 mg / 1 ml

(Ketorolac tromethamine)

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 KETROMINE IS AND WHAT IT IS USED FOR

Ketromine contains the active substance ketorolac tromethamine.

Ketorolac tromethamine is a non-steroidal anti-inflammatory drug, which is used in the short-term management of moderate to severe postoperative pain.

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

2. BEFORE YOU TAKE KETROMINE

Do not take Ketromine if you:

- are allergic to ketorolac tromethamine or any of the excipients of Ketromine;
- are hypersensitive to aspirin or to any other NSAIDs, (allergic-type reaction, asthma, or urticaria in response to exposure to aspirin or other NSAIDs; severe, rarely fatal, anaphylactic-like reactions);
- have active or previous peptic ulcer, or any history of gastro-intestinal bleeding or perforation;
- suffer from severe heart failure;
- have confirmed or suspected cerebrovascular bleeding, hypovolaemia or dehydration;
- have nasal polyps, hemorrhagic diathesis (including coagulation disorders);
- have renal impairment, advanced, or risk of renal failure due to volume depletion;
- are pregnant or in labor (increased risk of uterine hemorrhage and risk for adversely affecting fetal circulation);
- are breastfeeding;
- are taking aspirin, other non-steroidal anti-inflammatory drugs, pentoxifylline and probenecid (the concomitant use of these medicines with Ketromine is contraindicated).

Ketromine is also contraindicated as a prophylactic analgesic before surgery and for intraoperative use due to its anticoagulant effect and it should also not be given postoperatively to patients who have undergone procedures with a high risk of haemorrhage.
Neuroaxial (epidural or intrathecal) administration of Ketromine is contraindicated.

Take special care with Ketromine

Ask your doctor before taking Ketromine.
Non-selective NSAIDs are associated with a small increased risk of thrombotic events even when used short-term in those with no cardiovascular risk factors.
The lowest effective dose of NSAIDs should be prescribed for the shortest period to control symptoms and the need for long-term treatment should be reviewed periodically.
The recommended maximum duration for parenteral therapy is 2 days, and patients should be transferred to oral therapy as soon as possible; oral use should not exceed 7 days.

Non-steroidal anti-inflammatory drugs should be used with caution in patients with hepatic impairment; there is an increased risk of gastro-intestinal bleeding and fluid retention.
Ketromine should be withdrawn if clinical symptoms of hepatotoxicity develop.
NSAIDs also should be used with caution in the elderly (risk of serious side effects and fatalities), in patients with allergic disorders, blood coagulation defects and connective-tissue disorders.
In patients with cardiac impairment, caution is required since their condition can be aggravated.
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 (patients with mild renal impairment should receive a reduced dose of Ketromine and undergo close monitoring of renal function).
The use of a NSAID in patients with active or previous gastro-intestinal ulceration or bleeding should be avoided and it is recommended to withdraw them if gastro-intestinal lesions develop.
Nevertheless patients with serious rheumatic diseases (e.g. rheumatoid arthritis) are usually dependent on NSAIDs treatment. For this reason, patients who need non-steroidal anti-inflammatory drugs treatment and have a risk of gastro-intestinal ulceration (including the elderly), are recommended to receive gastroprotective treatment.
Concomitant use of a NSAID 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 monitored closely.
Ketromine contains ethanol 96%, thus special care should be taken in children and high-risk groups such as patients with liver disease or epilepsy. Ethanol 96% is harmful for those suffering from alcoholism.
The total daily dose of Ketromine should be reduced in the elderly and in patients weighing less than 50 kg.

Taking other medicines

Please contact your doctor or pharmacist if you are taking, have recently taken or might take other medicines, including those obtained without a prescription. It is especially important for your doctor to be aware of the fact that you are being treated with:

- **analgesics**, avoid concomitant use of ketorolac with other NSAIDs and aspirin (increased side effects and haemorrhage);
- **anticoagulants**, increased risk of haemorrhage when ketorolac given with anticoagulants (avoid concomitant use, including low-dose heparins);
- **diuretics**, risk of nephrotoxicity of NSAIDs increased by diuretics, also ketorolac antagonizes the effects of diuretics;
- **lithium**, ketorolac reduces the excretion of lithium (increased risk of toxicity); avoid concomitant use;
- **pentoxifylline**, increased risk of bleeding when ketorolac given with pentoxifylline (avoid concomitant use);
- **probenecid**, excretion of ketorolac reduced by probenecid (increased plasma concentration); avoid concomitant use.

Taking Ketromine with food and drinks

Not applicable.

Pregnancy, breastfeeding and fertility

Pregnancy

It is recommended to avoid using non-steroidal 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 which the fetus is exposed.

The use of non-steroidal anti-inflammatory drugs is contraindicated during the last 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.

Ketromine contains ethanol 96%, so special care should be taken in pregnant women.

Breastfeeding

Because the data for the use of ketorolac during breastfeeding are controversial and the fact that this medicine contains ethanol 96%, it is recommended to avoid use during this period.

Fertility

Long-term use of some non-steroidal anti-inflammatory drugs might reduce female fertility which is reversible on stopping treatment.

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

Driving and using machines

Ketromine causes dizziness and drowsiness, thus affecting the performance of skilled tasks such as driving and using machines.

Important information for some of the excipients of Ketromine

Ketromine contains ethanol 96%. Ethanol is harmful for those suffering from alcoholism. Special caution should be taken into account in pregnant or breastfeeding women, children and high risk groups such as patients with liver disease or epilepsy.

3. HOW TO TAKE KETROMINE

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

Because of concerns over the high incidence of reported adverse effects with ketorolac, its dosage and maximum duration of use are restricted. The recommended maximum duration for parenteral therapy is 2 days and patients should be transferred to oral therapy as soon as possible and the oral use is limited to 7 days.

Adults and children over 16 years

By intramuscular injection or by intravenous injection: it is injected over at least 15 seconds, initially 10 mg, then 10 – 30 mg every 4 – 6 hours as required (up to every 2 hours during initial

postoperative period); maximum 90 mg daily (elderly and patients weighing less than 50 kg maximum 60 mg daily).
Maximum duration of treatment is 2 days.

Children under 16 years
Safety and efficacy in children have not been established. Therefore, Ketromine solution for injection is not recommended for use in children under 16 years of age.

If you take more Ketromine than you should
If you take more Ketromine 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.
Overdose with Ketromine has been variously associated with abdominal pain, nausea, vomiting, hyperventilation, peptic ulcers and / or erosive gastritis and renal dysfunction which are reversible on stopping treatment.
Dialysis does not significantly clean ketorolac from the bloodstream.

If you forget to take Ketromine
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 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, Ketromine can cause side effects, although not everybody gets them. Possible side effects of Ketromine are:
Gastro-intestinal disorders: gastro-intestinal bleeding (especially in the elderly), perforation, peptic ulceration, taste disturbances, melena, abdominal pain, constipation, diarrhea, flatulence, heartburn, indigestion, nausea, stomatitis and vomiting.
Skin disorders: severe skin reactions including Stevens-Johnson syndrome and Lyell's syndrome, erythroderma, toxic epidermal necrolysis, pruritus and rash.

Blood disorders: thrombocytopenia, epistaxis, inhibition of platelet aggregation, increased bleeding time, postoperative wound haemorrhage, haematoma, anemia and purpura.
Cardiovascular disorders: myocardial infarction, thrombotic tendency observations, edema, hypertension, bradycardia, chest pain, palpitations and pallor.
Central nervous system disorders: drowsiness, dizziness, headache, fever, convulsions, aseptic meningitis, euphoria, psychosis, abnormal dreams, hyperkinesia, confusion and hallucinations.
Hepatic disorders: hepatic necrosis, hepatitis, increased liver function tests, jaundice, liver failure.
Renal disorders: fluid retention, increases in blood urea and creatinine, acute renal failure, urinary retention and nephrotic syndrome.
Metabolism and nutrition disorders: hyponatraemia, hyperkalaemia.
Eye disorders: abnormal vision, visual disturbances and optic neuritis.
Immune system disorders: hypersensitivity reactions such as anaphylaxis, bronchospasm, laryngeal oedema and hypotension.
Respiratory disorders: asthma, dyspnea and pulmonary edema.
Other adverse effects: injection site pain, sweating, myalgia, thirst, etc.
Tell your doctor or pharmacist if you experience these side effects or if you notice any other side effect not listed in this leaflet.

5. HOW TO STORE KETROMINE

Keep out of the sight and reach of children.
Do not use Ketromine after the expiry date which is stated on the package.
Store below 25°C.
Store in the original packaging.

6. OTHER INFORMATION

What Ketromine 30 mg / 1 ml solution for injection contains
The active substance is ketorolac tromethamine.
1 ampoule 1 ml contains 30 mg of ketorolac tromethamine.
The excipients are: citric acid monohydrate, ethanol 96%, sodium hydroxide, water for injection.

Content of the pack

Carton box with 10 ampoules of 1 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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