KETOROLAC TROMETAMOL 30MG/ML SOLUTION FOR INJECTION
(Referred to in this leaflet as Ketorolac Injection)

Please read this leaflet carefully before being given Ketorolac Injection.

- Keep the leaflet in case you want to refer to it again
- If you want to know more about your medicine or have any questions, you should ask your doctor or pharmacist.

In this leaflet:
1. What Ketorolac Injection is and what it is used for
2. What you need to know before you are given Ketorolac Injection
3. How Ketorolac Injection should be given
4. Possible side effects
5. Storing Ketorolac Injection
6. Contents of the pack and other information

1. WHAT KETOROLAC INJECTION IS AND WHAT IT IS USED FOR

Ketorolac belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).
Ketorolac Injection is used to relieve moderate or severe pain after a surgical operation.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN KETOROLAC INJECTION

You must not be given Ketorolac Injection and you should talk to your doctor immediately if you:

- are allergic to Ketorolac or any of the ingredients of this medicine (see section 6)
- have had a hypersensitivity reaction to ibuprofen, aspirin or other NSAIDs
- have previously had or have peptic ulcers (ulcer in your stomach or duodenum), bleeding in your stomach or perforation
- have or have ever had bleeding from the stomach or perforation related to use of NSAIDs
- have bleeding from a damaged blood vessel in the brain
- have problems with bleeding or blood clotting disorders
- have nasal polyps, allergic swellings (of the skin, around the mouth, eyes, nose or the genitals) or constriction of the airways making breathing difficult
- have asthma or a history of asthma
- are taking other NSAIDs (such as ibuprofen), aspirin, oxpenthifyline (to treat circulatory disease), probenecid (to treat gout) or lithium salts (to treat nervous disorders)
- are taking medicines to thin the blood (such as warfarin or low dose heparin)
- are dehydrated or have lost a lot of blood
- have severe heart failure
- have liver failure

Information for Healthcare Professionals:

KETOROLAC TROMETAMOL 30MG/ML SOLUTION FOR INJECTION

Please read this information carefully before using Ketorolac Injection. Further information is contained in the Summary of Product Characteristics

PRESENTATION

Ketorolac Trometamol 30mg/ml Solution for Injection (referred to as Ketorolac Injection) contains 30mg ketorolac trometamol in each 1 ml ampoule. Also contains ethanol, sodium chloride, sodium hydroxide and water for injections.

DOSEAGE AND METHOD OF ADMINISTRATION

Ketorolac Injection is suitable for use as long as it remains clear and free of precipitate. Ketorolac Injection is for administration by intramuscular or bolus intravenous injection. Bolus intravenous doses should be given over at least 15 seconds. Ketorolac Injection should not be used for epidural or spinal administration.
The time to onset of analgesic effect following both IV and IM administration is approximately 30 minutes, maximum analgesia occurs within one to two hours. Analgesia normally lasts for four to six hours.

Adults: The recommended initial dose of Ketorolac Injection is 10mg followed by 10 to 30mg every four to six hours as required. In the initial post-operative period, Ketorolac Injection may be given as often as every two hours if needed. The lowest effective dose should be given. A total daily dose of 90mg for non-elderly and 60mg for the elderly, patients with renal impairment and patients less than 50kg should not be exceeded. The maximum duration of treatment should not exceed two days.
Opioid analgesics (e.g. morphine, pethidine) may be used concomitantly. When used with ketorolac, the daily dose of opioid is usually less than that normally required but opioid side effects should still be considered. Elderly patients should be monitored for GI bleeding.

Patients receiving Ketorolac Injection and oral ketorolac should receive a total combined daily dose not exceeding 90mg (60mg for the elderly, patients with renal impairment and patients less than 50kg). The oral component should not exceed 40mg on the day the change of formulation is made. Patients should be converted to oral treatment as soon as possible.

Children: Ketorolac Injection is not recommended for use in children under 16 years of age.

CONTRA-INDICATIONS

- have recently had an operation with a high risk of bleeding or bleeding that has not been completely stopped
- are about to have surgery
- have moderate or severe kidney disease, are at risk of, or have kidney failure
- are pregnant, in labour, in delivery or breast feeding
- are under 16 years of age.

Ketorolac Injection contains alcohol and is therefore not for epidural or intrathecal use (injection into the spine)

Before you are given Ketorolac Injection, tell your doctor if you:

- have stomach problems, inflammatory bowel disease (e.g. ulcerative colitis or Crohn's disease) or are passing black tarry stools or blood
- have problems with your kidneys or liver
- have problems breathing
- have heart problems or high blood pressure. Medicines such as Ketorolac Injection may be associated with a small increased risk of heart attack (“myocardial infarction”) 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 of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- have a decrease in the usual amount of urine you pass
- have bleeding or bruising at the site of your operation
- have systemic lupus erythematosus or mixed connective tissue disorder (autoimmune diseases)
- are elderly
- are planning to become pregnant.

Pregnancy and breast-feeding

Ketorolac Injection should not be given if you are pregnant, in labour, during delivery or if you are breast-feeding. Ketorolac may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Ketorolac Injection may make you feel dizzy, tired or drowsy, you may also get headaches, visual disturbances, vertigo or have difficulty sleeping. If you experience any of these you should not drive or operate machines.

Important information about some of the ingredients of Ketorolac Injection

This medicinal product contains 100mg of ethanol (alcohol) per dose, equivalent to 2ml beer or 1 ml wine per dose.

This may be harmful for those suffering from alcoholism, and should be taken into account in children and high-risk groups such as those with liver disease, or epilepsy.

Continued overleaf....
Other medicines and Ketorolac Injection

See Section 2 for medicines that should not be taken with Ketorolac Injection.

Tell your doctor if you are taking, or have recently taken, any other medicine – even those not prescribed. This is important because ketorolac could alter how other medicines work.

These include medicines for:

- blood clots (anti-coagulants, oxapenflavine, antiplatelet agents)
- heart failure (furosemide, diuretics or cardiac glycosides such as digoxin)
- depression (lithium, selective serotonin reuptake inhibitors - SSRI)
- high blood pressure (diuretics, ACE inhibitors, thromboxane, angiotensin II inhibitors)
- gout (probenecid), psoriasis (methotrexate), inflammation or arthritis (steroids)
- other NSAIDs (such as ibuprofen) or aspirin
- acute organ rejection (ciclosporin, tacrolimus)
- infections (quinolone antibacterials)
- HIV and AIDS (zidovudine)
- or a drug called mifepristone (used to induce abortion, usually through hospitals).

Ketorolac should not be used for 8 - 12 days after taking mifepristone.

3. HOW KETOROLAC INJECTION SHOULD BE GIVEN

You will normally be given Ketorolac Injection whilst in hospital. A doctor or nurse will give the injection into a muscle or a vein.

The usual dose is 10mg initially, followed by 10-30mg every 4 to 6 hours. The dose may be lowered if you are over 65 years of age, you have kidney problems or if you weigh less than 50kg.

The maximum duration of treatment should not be more than 2 days.

If you have the impression that the effect of Ketorolac Injection is too strong or too weak, talk to your doctor.

4. POSSIBLE SIDE EFFECTS

Like other medicines, Ketorolac Injection may cause side effects in some patients. Most patients are given ketorolac without experiencing problems.

Serious side effects

Tell your doctor IMMEDIATELY if any of the following occur:

- difficulty in breathing or wheezes, swelling of the face, lips or throat, itching or flaky skin, rash, spots or blisters on the skin. You may have an allergic reaction, which can be very serious
- you pass blood in your faeces (stools/motions)
- you pass black tarry stools
- you vomit any blood or dark particles that look like coffee grounds.
- serious illness with blistering of the skin, mouth, eyes and genitals called Stevens-Johnson Syndrome

Other side effects

Tell your doctor or nurse if you have any of the following:

- feeling sick or being sick, indigestion or heart burn, stomach pain or discomfort, inflammation of the stomach, bleeding, problems with the pancreas, stomach ulcer,
- diarrhea, belching, constipation or wind, feeling of fullness, feeling unwell
- anxiety, drowsiness, tiredness, dizziness, headache, sweating, fever, agitation, nervousness, mental disturbances, mood changes, confusion, abnormal thinking and feelings, inability to concentrate, inability to sleep, convulsions, giddiness, hyperactivity, a mild form of meningitis, hallucinations, abnormal dreams
- dry mouth, mouth ulcers, sore throat, excessive thirst, weight gain, fever, alterations of vision, taste or hearing (loss of hearing, ringing in the ears, vertigo)
- muscle pain, numbness or tingling, muscle spasms or weakness
- kidney problems, a change in the amount of urine passed or frequency in going to the toilet, blood in the urine, fluid retention, weight gain, kidney pain or kidney failure
- facial redness or paleness, flushing, bruising, anaemia, changes in the blood
- changes in blood pressure, palpitations, chest pain or slow heart beat.
- Medicines such as Ketorolac Injection may be associated with a small risk of increased heart attack ("myocardial infarction") or stroke
- bleeding from the site of the operation or bruising or a nose bleed
- sensitivity of the skin to light
- female infertility
- pain at the site of injection
- jaundice (yellowing of the skin and whites of the eyes), liver failure and inflammation of the liver have been reported very rarely.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. STORING KETOROLAC INJECTION

The hospital will store the medicines. Ketorolac Injection should not be stored above 30°C. It should be kept in the original container and protected from light. Keep out of reach and sight of children.

Use by date: Ketorolac Injection should not be used after the date on the carton.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What is in this medicine:

Each 1 ml ampoule contains 30mg of the active ingredient ketorolac trometamol.

The ampoules also contain ethanol, sodium chloride, sodium hydroxide and water for injections.

What this medicine looks like and contents of the pack:

Ketorolac Injection is a colourless or slightly yellowish solution in amber glass ampoules. Each pack contains 6 or 100 ampoules.


Manufacturer: Laboratorio Reig Jofre S.A, Barcelona, Spain.

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As with all NSAIDs caution is advised when ciclosporin or tacrolimus is co-administered because of the increased risk of nephrotoxicity.

NSAIDs should not be used for 8-12 days after mifepristone. NSAIDs can reduce the effects of mifepristone.

Caution should be taken when co-administering with corticosteroids because of the increased risk of GI bleeding.

Patients taking quinolones may have an increased risk of developing convulsions because of an increased tendency to bleeding co-administration with oxapenflavine should be avoided.

In patients receiving lithium there is a possible inhibition of renal lithium clearance, leading to an increased plasma lithium concentration.

Antiplatelet agents and SSRIs may increase the risk of GI bleeding.

Co-administration with Zidovudine may result in haematological toxicity.

INCOMPATIBILITIES

Ketorolac Injection should not be mixed in a small volume (e.g. in a syringe) with morphine sulfate, pethidine hydrochloride, promethazine hydrochloride or hydroxyzine hydrochloride, as precipitation of ketorolac will occur.

Ketorolac Injection is compatible with normal saline, 5% dextrose, Ringer's, lactated Ringer's or Plasmaeyte solutions. Compatibility of Ketorolac Injection with other drugs is unknown.

Beacon PHARMACEUTICALS