Package leaflet: Information for the user

Ketorolac Trometamol 30 mg/ml solution for injection

Ketorolac Trometamol

The name of your medicine is Ketorolac Trometamol 30 mg/ml solution for injection, which will be referred to as Ketorolac throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Ketorolac is and what it is used for
2. What you need to know before you take Ketorolac
3. How to take Ketorolac
4. Possible side effects
5. How to store Ketorolac
6. Contents of the pack and other information

1. What Ketorolac is and what it is used for

Ketorolac contains a medicine called ketorolac trometamol. This is a 'Non Steroidal Anti Inflammatory Drug' or NSAID. Ketorolac is used in hospital, for pain relief after operations. Ketorolac can lessen pain, swelling, redness and heat (inflammation).

2. What you need to know before you take Ketorolac

Do not have this medicine and tell your doctor if:

- **you are allergic (hypersensitive) to** Ketorolac trometamol or any of the other ingredients of Ketorolac (listed in Section 6).
- **you are allergic (hypersensitive) to** acetylsalicylic acid or other NSAIDs (such as ibuprofen or diclofenac).
- You are aged under 16.
- You now have or have ever had any problems with your stomach or gut (intestine) like an ulcer or bleeding.
- You have **severe** problems with your liver or heart.
- You have **moderate or severe** problems with your kidneys.
- You have ever had bleeding in your brain.
- You have a problem that causes you to bleed easily, including a condition like haemophilia.
- You are taking medicines to stop your blood clotting, like warfarin, heparin or clopidogrel.
- You have asthma or allergies (like hayfever) or have had swelling of the face, lips, eyes or tongue in the past.
- You have or have had lumps in your nose (polyps).
- You are taking other NSAIDs, like ibuprofen or acetylsalicylic acid
- You are taking oxpentifylline (for your circulation), probenecid (for gout) or lithium (for mental health problems).
- You plan to get pregnant, are pregnant, in labour or are breast-feeding.
- You are about to have an operation.
- You have been advised you have a high risk of bleeding after an operation or are still bleeding after an operation.

You must not be given Ketorolac if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given Ketorolac.

Warnings and precautions

Talk to your doctor or nurse before taking Ketorolac. If you have heart problems, previous stroke or think that 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 nurse.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Ketorolac, as Ketorolac can sometimes worsen wound healing in your gut after surgery.

Check with your doctor or nurse before taking Ketorolac if any of the following apply to you:

- You are elderly (you are more likely to suffer problems).
- Problems with your kidneys or liver.
- High blood pressure.
- Problems with the blood vessels (arteries) anywhere in your body.
- Too much fat (lipid) in your blood (hyperlipidaemia).
- An autoimmune condition, such as 'systemic lupus erythematosus' (SLE, which causes joint pain, skin rashes and fever) and colitis or Crohn's disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss).

If you are not sure if any of the above applies to you, talk to your doctor or nurse before being given Ketorolac.

Other medicines and Ketorolac

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or nurse if you are taking any of the following medicines before you are given Ketorolac:

- Other NSAIDs, like acetylsalicylic acid, ibuprofen or diclofenac.
- Medicines to stop your blood clotting, like warfarin, heparin or clopidogrel.
- Oxpentifylline (for your circulation).
- Probenecid (for gout).
- Lithium (for mental health problems).

If you are taking any of the above medicines **you must not be given Ketorolac.**

Tell your doctor or nurse if you are taking:

- An 'ACE inhibitor' or other medicine for high blood pressure, like cilazapril, enalapril or propranolol.
- A diuretic (water tablet) (for high blood pressure), like furosemide.
- A 'cardiac glycoside' (for heart problems), like digoxin.
- A steroid (for swelling and inflammation), like hydrocortisone, prednisolone and dexamethasone.
- A 'quinolone antibiotic' (for infections), like ciprofloxacin or moxifloxacin.
- Certain medicines for mental health problems 'SSRIs', like fluoxetine or citalopram.
- Methotrexate (used to treat skin problems, arthritis or cancer).
- Ciclosporin or tacrolimus (for skin problems or after an organ transplant).
- Zidovudine (used to treat AIDS and HIV infections).
- Mifepristone (used to end pregnancy or to bring on labour if the baby has died).

If any of the above apply to you, or if you are not sure, talk to your doctor or nurse before you are given Ketorolac.

Pregnancy, breast-feeding and fertility

Ketorolac may make it more difficult to become pregnant. You must not be given Ketorolac if you are pregnant, in labour or are breastfeeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines:

Ketorolac may make you tired, drowsy, dizzy, have problems with your balance or eyesight, depressed or have difficulty sleeping. Talk to your doctor if any of these happen to you and do not drive or use any tools or machines.

Ketorolac contains sodium and alcohol:

Ketorolac is essentially 'sodium free' as it contains less than 1 mmol sodium (23 mg per 1 ml). This medicine contains a small amount of ethanol (alcohol), 100mg per dose.

3. How to take Ketorolac

Medicines such as Ketorolac may be associated (linked) with a small increased risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with higher doses and prolonged (longer term) treatment.

Ketorolac will be given to you by a doctor or nurse. It will be given to you by injection into a muscle (such as into your arm) or into a vein. The maximum length of treatment should be two days.

Children

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

Adults

- The usual starting dose is 10 mg.
- This can be followed by a dose of 10 to 30 mg every 4 to 6 hours, as needed.
- The maximum dose is 90 mg each day.
- Your doctor may also give you other pain killers (such as pethidine or morphine) if your pain is severe.

People over 65 years of age, or with kidney problems or who weigh less than 50 kg.

- Your doctor will usually give you doses lower than those described for adults.
- The maximum dose is 60 mg each day.
- Your doctor may also give you other pain killers (such as pethidine or morphine) if your pain is severe.Your doctor may also give you other pain killers (such as pethidine or morphine) if your pain is severe.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines Ketorolac can cause side effects, although not everyone will get them. Medicines such as Ketorolac may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

Important side effects to look out for:

Tell a doctor or nurse straight away if any of the following side effects happen. You may need urgent medical treatment:

Serious stomach or gut problems, signs include:

- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut. This may be seen as upset stomach with stomach pain, fever, feeling or being sick.

This information is intended for medical or healthcare professionals only:

The tear-off portion above is intended for the patient

INFORMATION FOR HEALTHCARE PROFESSIONALS

Ketorolac Trometamol 30 mg/ml solution for injection

Ketorolac Trometamol

Please refer to the Summary of Product Characteristics for full prescribing information.

Presentation

Glass ampoules containing 30 mg/ ml ketorolac trometamol. The solution is clear and slightly yellow in colour. Excipients are ethanol, sodium chloride and water for injections. Cartons of 5, 10 & 25 ampoules. Not all pack sizes may be marketed.

Important information about the excipients in Ketorolac Ampoules.

Each Ketorolac 30 mg/ ml ampoule contains 100 mg ethanol and 4.35 mg sodium chloride.

Posology and method of administration

Ketorolac is for administration by intramuscular or bolus intravenous injection. Bolus intravenous doses should be given over no less than 15 seconds. Ketorolac should not be used for epidural or spinal administration.

The time to onset of analgesic effect following both IV and IM administration is similar and is approximately 30 minutes, with maximum analgesia occurring within one to two hours. The median duration of analgesia is generally four to six hours.

Dosage should be adjusted according to the severity of the pain and the patient response.

The administration of continuous multiple daily doses of ketorolac intramuscularly or intravenously should not exceed two days because adverse events may increase with prolonged usage. There has been limited experience with dosing for longer periods since the vast majority of patients have transferred to oral medication, or no longer require analgesic therapy after this time.

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms

Adults

The recommended initial dose of Ketorolac is 10 mg, followed by 10 to 30 mg every four to six hours as required. In the initial post-operative period, Ketorolac may be given as often as every two hours if needed. The lowest effective dose should be given. A total daily dose of 90 mg for non-elderly and 60 mg for the elderly, renally-impaired patients and patients less than 50 kg should not be exceeded. The maximum duration of treatment should not exceed two days.

Reduce dosage in patients under 50 kg.

For patients receiving parenteral Ketorolac, and who are converted to Ketorolac 10 mg tablets, the total combined daily dose should not exceed 90 mg (60 mg for the elderly, renally-impaired patients and patients less than 50 kg) and the oral component should not exceed 40 mg on the day the change of formulation is made. Patients should be converted to oral treatment as soon as possible.

- Problems with your pancreas, seen as severe stomach pain which spreads to your back.
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.

Allergic reactions, signs include:
- Sudden swelling of your throat, face, hands or feet.
- Difficulty breathing, tightness in your chest.
- Skin rashes, blisters or itching.

Severe skin rashes, signs include:
- A severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes. Fever, headache, cough and aching body may happen at the same time.

Heart attack, signs include:
- Chest pain which may spread to your neck and shoulders and down your left arm.

Stroke, signs include:
- Muscle weakness and numbness. This may only be on one side of your body.
- A suddenly altered sense of smell, taste, hearing or vision, confusion.

Meningitis, signs include:
- Fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

Liver problems, signs include:
- Yellowing of your skin or the whites of your eyes (jaundice).
- Feeling tired, loss of appetite, feeling or being sick and pale coloured stools (hepatitis) and problems (including hepatitis), shown in blood tests.

Problems passing water (urine), signs include:
- A feeling of fullness and a need to empty your bladder, but then difficulty in emptying it.

If you notice any of the serious side effects mentioned above, tell your doctor or nurse straight away.

Other possible side effects:

Stomach and gut
- Heartburn, indigestion, stomach ache, feeling sick or being sick, constipation, diarrhoea, wind.
- Burping or a feeling of fullness.

Blood
- Bleeding from your wound after an operation or nosebleeds.
- A swelling filled with blood.
- Blood problems, like too much potassium or not enough sodium.
- Blood problems, like anaemia, not enough platelets or changes to the numbers of white blood cells.

Mental illness
- Having difficulty sleeping or changes in your patterns of dreaming.
- Depression.
- Feeling worried (anxious) or nervous or extremely happy (euphoria).
- Seeing and possibly hearing things that are not really there (hallucinations).
- Mental problems which may make you feel confused, restless and disturbed (agitated) and lose contact with reality.

Nervous system
- Headache.
- Fits or seizures, feeling dizzy or light-headed or sleepy.
- Pins and needles or numbness of your hands and feet.
- Difficulty with your memory or concentration.

Eyes and ears
- Changes to your eyesight, eye pain.
- Changes to your hearing, including ringing in the ears (tinnitus) and hearing loss.
- Dizziness that causes problems with your balance.

Heart and circulation
- Swelling of your hands, feet or legs (oedema). This may be with chest pains, tiredness, shortness of breath (cardiac failure).
- A fluttering feeling in your heart (palpitations) slow heart beat or high blood pressure.
- Problems with the way your heart pumps blood around the body. Signs may include tiredness, shortness of breath, feeling faint.

Chest
- Difficulty breathing, including shortness of breath, wheezing or coughing.
- Swelling of your lungs.

Skin and hair
- Light sensitivity, skin rashes including redness, hives, pimples and blisters on your body and face.
- Itching or sweating, pale skin or redness of the face and neck (flushing).

Urinary
- Blood in your water (urine) or kidney problems.
- Going to the toilet more often to pass water, or going less often.
- Pain in your side.

Other
- Pain where the injection was given.
- Thirst, dry mouth, taste changes, fever, weight gain or weight loss.
- Feeling tired or generally unwell.
- A sore mouth.
- Muscle spasms, pain or weakness.
- Problems for women in getting pregnant.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly (See details below).

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

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

1400000XXXX

5. How to store Ketorolac

Your pharmacist is responsible for storing Ketorolac. They are also responsible for disposing of any unused Ketorolac correctly.

Keep this medicine out of the sight and reach of children.

Ketorolac should not be used after the expiry date which is stated on the carton and on the label. The expiry date refers to the last day of that month.

Keep the ampoules in the original package to protect from light. This medicinal product does not require any special storage conditions. Do not refrigerate or freeze. Do not use if particulate matter is present.

For single use. Any unused solution must be discarded.

After opening the product must be used immediately.

Dilutions with 0.9% normal saline, 5% dextrose, Ringer's and lactated Ringer's solution. The mixture must be administered within 48 hours after preparation.

From a microbiological point of view, unless the method of opening and dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Contents of the pack and other information

What Ketorolac contains

The active substance in 'Ketorolac Trometamol 30 mg/ml solution for injection' is ketorolac trometamol. Each 1 ml of solution contains 30 mg (milligrams) of ketorolac trometamol, respectively.

Other ingredients are ethanol, sodium chloride, Hydrochloric acid (for pH adjustment), Sodium hydroxide (for pH adjustment) and water for injections.

What Ketorolac looks like and contents of the pack

Ketorolac is a clear, slightly yellow solution.

Ketorolac is supplied in glass ampoules containing 1 ml of solution, in pack of 5, 10 & 25.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Baxter Healthcare Limited
Caxton Way,
Thetford, Norfolk IP24 3SE,
United Kingdom.

Manufacturer
Baxter
Boulevard René Branquart, 80
7860 Lessines
Belgium

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Elderly

The elderly are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest effective dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy. A total daily dose of 60 mg should not be exceeded.

Children

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

Renal impairment

Contra-indicated in moderate to severe renal impairment; reduce dosage in lesser impairment (not exceeding 60 mg/day IV or IM).

Special dosage instructions

Opioid analgesics (e.g. morphine, pethidine) may be used concomitantly, and may be required for optimal analgesic effect in the early post-operative period when pain is most severe. Ketorolac does not interfere with opioid binding and does not exacerbate opioid-related respiratory depression or sedation. When used in association with Ketorolac ampoules, the daily dose of opioid is usually less than that normally required. However, opioid side-effects should still be considered, especially in day-case surgery.

Mode of administration

Ketorolac is for administration by intramuscular or bolus intravenous injection. Bolus intravenous doses should be given over no less than 15 seconds. Ketorolac should not be used for epidural or spinal administration.

Do not use Ketorolac Ampoules if particulate matter is present.

Ketorolac is compatible with 0.9% normal saline, 5% dextrose, Ringer's, lactated Ringer's solutions. Compatibility of Ketorolac with other drugs is unknown.

Incompatibilities

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

Shelf life

Unopened: 24 Months

After opening: The product must be used immediately.

After dilution: Chemical and physical in-use stability has been demonstrated for 48 hours at 25ºC.

Special precautions for storage

Keep the ampoules in the original package to protect from light. This medicinal product does not require any special storage conditions. Do not refrigerate or freeze. Do not use if particulate matter is present.