Ketorolac Trometamol

Kortezor®

30 mg/mL solution for intramuscular (IM)/intravenous (IV) injection
Nonsteroidal anti-inflammatory drug / Analgesic / Antipyretic

FORMULATION

Each mL solution for injection contains:

Ketorolac trometamol	30 mg
Alcohol	12 %

PRODUCT DESCRIPTION

Ketorolac trometamol (Kortezor®) is a clear, slightly yellow, sterile, aqueous solution, free from extraneous matter and filled in a 2 mL clear ampule with blue dot.

PHARMACODYNAMICS

Ketorolac trometamol exhibits anti-inflammatory, analgesic and antipyretic activities by inhibiting cyclooxygenase (COX)-1 and COX-2 isoenzymes. These enzymes are found throughout the body and produce prostaglandins, which are important mediators of pain, fever, and adaptive and protective reactions in many organs and (inflamed) tissues.

The greatest difference between large and small doses of ketorolac trometamol is in the duration of analgesia.

PHARMACOKINETICS

Following IV administration of 15 or 30 mg doses of ketorolac trometamol injection in healthy adults, time to peak plasma concentration was about 1 to 3 minutes, with peak plasma concentrations of approximately 2.5 or 4.7 mcg/mL, respectively.

Ketorolac trometamol is rapidly and completely absorbed when administered by the IM route. The pharmacokinetics is linear following single and multiple dosing. After single IM ketorolac doses of 10 mg, 30 mg or 60 mg, peak plasma concentrations at 30 to 60 minutes are 0.7 to 1.4, 2.2 to 3, and 4 to 4.6 mcg/L, respectively.

Ketorolac is not widely distributed following IM or IV administration. The apparent volume of distribution during the terminal elimination phase in healthy adults is approximately 0.15 to 0.3 L/kg and the volume of distribution at steady state (Vss) is about 0.11 to 0.33 L/kg. The drug also crosses the blood-brain barrier poorly, with cerebrospinal fluid concentrations reported to be about 0.2% of concurrent plasma concentrations. Ketorolac is more than 99% protein bound.

Ketorolac crosses the placenta and enters the fetal circulation to give fetal cord blood levels 11.6% (range 4 to 25%) of the corresponding maternal levels. There is very little excretion of ketorolac into breast milk, with peak milk ketorolac concentrations not exceeding 7.3 ng/mL after a single 10 mg oral dose, and the milk-to-plasma ratio was about 0.04.

Following single IM or IV doses of ketorolac trometamol in healthy adults, plasma concentrations of ketorolac decline in a biphasic manner with a terminal elimination half-life of about 4 to 6 hours. In renally impaired patients, there is a reduction in clearance and an increase in terminal half-life (see table below).

The drug undergoes hydroxylation in the liver to form p-hydroxyketorolac. This hydroxy metabolite exhibits limited pharmacologic activity, having less than 20% or 1% of the anti-inflammatory or analgesic potency, respectively, of the parent drug. Ketorolac also undergoes conjugation with glucuronic acid. The drug is also metabolized to unidentified polar metabolites, which appear to be pharmacologically inactive probably because of their high polarity and rapid elimination.

The primary route of excretion of ketorolac trometamol and its metabolites (conjugates and the p-hydroxy metabolite) is in the urine (91%) within 2 days and the remainder (6%) being excreted in the feces within 3 days. In healthy adults, a single IV dose is excreted in urine as ketorolac (56 to 60%), ketorolac glucoronide (20 to 26%), p-hydroxyketorolac (11 to 12%), and unidentified polar metabolites (6 to 7%).

The Influence of Age, Liver, and Kidney Function on the Clearance and Terminal Half-Life of Ketorolac in Adult Populations*

PATIENT GROUP	TOTAL CLEARANCE (L/hr/kg) Mean (Range)	TERMINAL HALF -LIFE (Hours) Mean (Range)
Normal Subjects	0.023 (0.01 to 0.046)	5.3 (3.5 to 9.2)
Healthy elderly subjects	0.019 (0.013 to 0.034)	7 (4.7 to 8.6)
Patients with hepatic dysfunction	0.029 (0.013 to 0.066)	5.4 (2.2 to 6.9)
Patients with renal impairment (serum creatinine= 1.9 to 5 mg/dL)	0.016 (0.005 to 0.043)	10.3 (5.9 to 19.2)
Renal dialysis patients	0.016 (0.003 to 0.036)	13.6 (8 to 39.1)

**Estimated from 30 mg single IM doses of ketorolac trometamol*

INDICATION

Short term (≤ 2 days) management of moderate to severe acute postoperative pain.

DOSAGE AND ADMINISTRATION

To minimize the potential risk for adverse effects, **the lowest effective dose of ketorolac should be used for the shortest possible time**. Therefore, after observing the response to initial therapy with this product, the dose and frequency should be adjusted to suit individual patient needs.

General Dosing Recommendation:

- Administration of IV or IM ketorolac should not exceed 2 days (see ***Boxed Warnings***).
- IV bolus must be given over no less than 15 seconds.
- Ketorolac ampules should not be used for epidural or spinal administration.
- IM administration should be given slowly and deeply into the muscle.
- Analgesic effect usually begins in about 30 minutes and peaks in 1 to 2 hours after IV or IM administration.
- The analgesic effect may be maintained up to 6 to 8 hours
- Adverse local effects may be minimized by applying pressure over the injection site for 15 to 30 seconds after administration.
- Strict aseptic technique should be observed when drawing up the contents of the ampule. As with all parenteral medicines, inspect ketorolac trometamol for injection visually for particulate matter and discoloration before administration.
- Each ampule is for single use only. The solution should be used immediately after opening. Any unused contents should be discarded.
- For patients converted from parenteral to oral ketorolac, the total dose should not exceed 90 mg (60 mg for elderly, renally-impaired and patients < 50 kg), and the oral dose should not exceed 40 mg on the day of change. Patients should be converted to oral treatment as soon as possible.
- 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. When used with ketorolac trometamol, the daily dose of opioid is usually less than normally required but adverse effects should still be considered.

Recommended Ketorolac Adult IV/IM Dose:

- Initially, 10 mg followed by 10 to 30 mg every 4 to 6 hours, as needed.
- In the initial postoperative period, ketorolac may be given as often as every two hours if needed.

Maximum Dose: *90 mg/day*

Special Populations:

Geriatric (>65 years old): A single dose with the lower end of the dosage range is recommended; the initial dose should be 10 mg

Maximum Dose: 60 mg/day

Renal Impairment: Ketorolac is contraindicated in moderate to severe renal impairment; reduce dosage in lesser renal impairment (not to exceed 60 mg/day IV or IM).

Or, as prescribed by a physician.

CONTRAINDICATIONS

- Known hypersensitivity to ketorolac trometamol or other ingredients in the product
- Patients with active peptic ulcer disease, recent gastrointestinal (GI) bleeding or perforation, or a history of recurrent ulceration or active inflammatory disease of the GI system.
- Patients with complete or partial syndrome of nasal polyps, or in whom asthma, anaphylaxis, urticaria, rhinitis, or other allergic-type reactions are precipitated by aspirin or other NSAIDs. Severe, rarely fatal, anaphylactoid reactions to NSAIDs have been reported in such patients.
- As a prophylactic analgesia before surgery and intra-operatively.
- For neuroaxial (epidural or intrathecal) administration due to its alcohol content
- Significant hepatic impairment, active liver disease or severe liver failure.
- Patients with moderate or severe renal impairment (serum creatinine>160 mcmol/L) or patients at risk of renal failure because of volume depletion or dehydration.
- Patients with suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis incomplete hemostasis, or patients at high risk of bleeding
- Patients with severe heart failure.
- Dengue fever, since NSAIDs may increase the risk of bleeding
- Patients receiving concomitant aspirin or NSAID therapy because of the cumulative risk of serious NSAID-related adverse effects.
- Concomitant treatment with probenecid, pentoxifylline or lithium salts
- In patients on anticoagulants including warfarin and low-dose heparin (2,500 to 5,000 units every 12 hours)
- Pregnancy, labor, delivery, or breastfeeding
- Children below 16 years old
- **Contraindicated in the treatment of perioperative pain in the setting of coronary artery by pass graft (CABG) surgery.**

WARNINGS AND PRECAUTIONS

Treatment with Ketorolac IM/IV should not exceed 2 days because adverse events may increase with prolonged use. There is limited experience with dosing for longer periods since after two days majority of patients no longer require analgesic therapy or are shifted to oral medication. The total duration of combined IM and oral treatment should not exceed 5 days.

Cardiovascular Risk

- NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction and stroke which can be fatal. All NSAIDs may have a similar risk. The risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

Gastrointestinal Risk

- NSAIDs, including ketorolac, cause an increased risk of serious GI adverse events including bleeding, ulceration and perforation of the stomach or intestines which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious GI events.

CARDIOVASCULAR EFFECTS *(see Boxed Warnings)*

Cardiovascular Thrombotic Events

Patients should remain alert for the signs and symptoms of serious arteriothrombotic events (e.g. chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings. Patients should be instructed to see a physician immediately in case of such an event.

There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAID use. The concurrent use of aspirin and an NSAID does increase the risk of serious GI events.

Hypertension

NSAIDs can lead to the onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of cardiovascular events. Patients taking thiazides or loop diuretics may have impaired response to these therapies when taking NSAIDs. NSAIDs, including ketorolac, should be used with caution in patients with hypertension. Blood pressure should be monitored closely during the initiation of NSAID treatment and throughout the course of therapy.

Congestive Heart Failure and Edema

Fluid retention and edema have been observed in some patients taking NSAIDs. Ketorolac should be used with caution in patients with fluid retention or heart failure.

NSAIDs have a potential risk of hyperkalemia, particularly in patients with conditions such as diabetes mellitus or renal failure; elderly patients; or in patients receiving concomitant therapy with beta-adrenergic blockers, angiotensin converting enzyme inhibitors or some diuretics.

Gastrointestinal Effects (see Boxed Warnings)

NSAIDs, including ketorolac, can cause an increased risk of serious GI adverse events including inflammation, bleeding, ulceration, and perforation of the stomach, small or large intestines, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs.

NSAIDs should be prescribed with extreme caution in those with a history of ulcer disease or GI bleeding since these patients have a greater than 10-fold increased risk for developing a GI bleed compared with patients with neither of these risk factors. Other factors that increase the risk for GI bleeding in patients treated with NSAIDs include concomitant use of oral corticosteroids or anticoagulants, longer duration of NSAID therapy, smoking, use of alcohol, older age, and poor general health status.

Physicians and patients should remain alert for signs and symptoms of GI ulceration and bleeding during NSAID therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. This should include discontinuation of the NSAID until a serious GI adverse event is ruled out. Alternate therapies that do not involve NSAIDs should be considered especially for high-risk patients.

Close medical surveillance and caution should be exercised in patients with ulcerative colitis or with Crohn's disease as these conditions may be exacerbated.

GENITOURINARY EFFECTS

Some NSAIDs are associated with persistent urinary symptoms (bladder pain, dysuria, urinary frequency), hematuria or cystitis. The onset of these symptoms may occur at any time after the initiation of therapy with an NSAID. Should urinary symptoms occur, treatment with ketorolac should be stopped to obtain recovery. This should be done before urological investigations or treatments are carried out.

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and angiotensin-converting enzyme (ACE) inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state.

As with other drugs that inhibit prostaglandin synthesis elevations of serum urea creatinine and potassium have been reported with ketorolac and may occur after one dose.

Patients with impaired renal function:

Ketorolac is CONTRAINDICATED in patients with severe renal disease (see **Contraindications**). Patients with lesser renal impairment should receive a reduced dose of ketorolac not exceeding 60 mg/day IM or IV and their renal status be closely monitored.

ANAPHYLACTOID REACTIONS (see *Contraindications*)

Anaphylactoid reactions may occur in patients without known prior exposure to NSAIDs. Ketorolac should not be given to patients with the aspirin triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs. Ketorolac should be administered with caution in patients with pre-existing asthma and emergency help should be sought in cases where an anaphylactoid reaction occurs.

SKIN REACTIONS

As with other NSAIDs, ketorolac, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN or Lyell's syndrome), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

HEPATIC EFFECTS

Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs including ketorolac. These laboratory abnormalities may progress, may remain unchanged, or may be transient with continuing therapy. In patients with chronic treatment with ketorolac, periodic monitoring of transaminases is recommended. Notable elevations of alanine aminotransferase (ALT) or aspartate aminotransferase (AST) (approximately three or more times the upper limit of normal) have been reported in approximately 2 to 4% of patients, including marked elevations (eight or more times the upper limit of normal) in about 1% of patients. Rare cases of severe hepatic reactions, including jaundice and fatal fulminant hepatitis, liver necrosis and hepatic failure, some with fatal outcomes have been reported.

Patients with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of a more severe hepatic reaction while on therapy with NSAIDs including ketorolac. Discontinue ketorolac if clinical signs and symptoms consistent with liver disease develop or if systemic manifestations occur (e.g., eosinophilia, rash).

HEMATOLOGIC EFFECTS

Anemia is sometimes seen in patients receiving NSAIDs including ketorolac. This may be due to fluid retention, occult or gross GI blood loss, or an incompletely described effect upon erythropoiesis. Patients on long-term treatment with NSAIDs, including ketorolac, should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia.

Ketorolac inhibits platelet aggregation and prolongs bleeding time. In patients with normal bleeding function, bleeding times were raised, but not outside the normal range of two to eleven minutes. Unlike the prolonged effects from aspirin, platelet function returns to normal within 24 to 48 hours after ketorolac is discontinued.

Postoperative wound hemorrhage has been reported in association with the immediate peri-operative use of ketorolac. Therefore, ketorolac should not be used in patients who have had operations with a high risk of hemorrhage or incomplete hemostasis. Caution should be used where strict hemostasis is critical (e.g., in cosmetic or day-case surgery).

Hematoma and other signs of wound hemorrhage and epistaxis have been reported with the use of ketorolac. Physician should be aware of the pharmacological similarity of ketorolac to other NSAIDs that inhibit COX and the risk of bleeding, particularly in the elderly ***(see Contraindications).***

ASEPTIC MENINGITIS

In occasional cases, with some NSAIDs, the symptoms of aseptic meningitis (stiff neck, severe headaches, nausea and vomiting, fever or clouding of consciousness) have been observed. Patients with autoimmune disorders (systemic lupus erythematosus, mixed connective tissues diseases, etc.) seem to be pre-disposed. Therefore, in such patients, the physician must be vigilant to the development of this complication.

INFECTION

As with other NSAIDs, ketorolac trometamol injection may mask the usual signs of infection.

OPHTHALMOLOGIC EFFECTS

Blurred and/or diminished vision has been reported with the use of ketorolac trometamol injection and other NSAIDs. If such symptoms develop, this drug should be discontinued and an ophthalmologic examination performed.

CONCOMITANT DISEASES *(see Contraindications)*

Ketorolac should be used very cautiously and with careful monitoring in patients who may be adversely affected by prolongation of bleeding time (e.g., patients receiving anticoagulants, patients with hemophilia, von Willebrand's disease, or platelet deficiency) and only when the potential benefits justify the possible risks to the patient, since the drug may inhibit platelet function and hemorrhage is possible.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

Dizziness, drowsiness, visual disturbance, headache, vertigo, insomnia and depression have been reported with ketorolac use. If patients experience these or other similar adverse effects, they should not drive or operate machinery.

INTERACTIONS WITH OTHER MEDICAMENTS

CONCOMITANT DRUGS	EFFECTS
ACE Inhibitors, Angiotensin-II Receptor Antagonists	Decreased hypotensive effect and increased risk of renal impairment, particularly in volume-depleted patients
Anticoagulants, Thrombolytics (e.g., warfarin, heparin)	CONTRAINDICATED; increased risk of GI adverse events such as ulceration and bleeding and may enhance anticoagulant effect
Anticonvulsants (e.g., phenytoin, carbamazepine)	Sporadic cases of seizure have been reported with concomitant use
Aspirin, NSAIDs	CONTRAINDICATED; increased side effects and hemorrhage
Ciclosporin, Tacrolimus	Increased risk of nephrotoxicity
Corticosteroids	Increased risk of gastrointestinal bleeding and ulceration
Digoxin	NSAIDs may exacerbate cardiac failure, reduce glomerular filtration rate (GFR) and increase plasma cardiac glycoside levels.
Diuretics (e.g., furosemide, thiazides)	Reduced diuretic effects and increased nephrotoxicity.
Lithium	CONTRAINDICATED; ketorolac reduces excretion of lithium (increased risk of toxicity)
Methotrexate	NSAIDs may reduce the excretion of methotrexate (increased risk of toxicity) . Caution should be exercised when ketorolac and methotrexate is given concomitantly.
Nondepolarizing Muscle Relaxants	May potentiate effects of relaxants, resulting in apnea
Pentoxifylline (oxpentifylline)	CONTRAINDICATED; increased risk of bleeding when ketorolac is given with pentoxifylline
Probenecid	CONTRAINDICATED; decreased clearance and increased plasma concentration, total AUC, and half-life of ketorolac
Psychoactive drugs (e.g., fluoxetine, thiothixene, alprazolam)	Concomitant administration produces hallucination.
Quinolones	Possible increased risk of convulsions
Selective Serotonin Reuptake Inhibitors	Increased risk of GI bleeding
Zidovudine	Increase the risk of hematologic toxicity

Tell your doctor if you are taking other medicines, including vitamins, supplements, and herbal medicines.

STATEMENT ON USAGE FOR HIGH RISK GROUPS

Pregnancy

Pregnancy Category C. Ketorolac trometamol is CONTRAINDICATED during pregnancy, labor or delivery. Avoid ketorolac use during pregnancy (particularly late pregnancy) because of the known effects of NSAIDs on the fetal cardiovascular system (closure of ductus arteriosus; see ***Contraindications***).

Labor and Delivery

Ketorolac should not be used during labor and delivery because it may adversely affect fetal circulation and inhibit uterine contractions through its effect on prostaglandin synthesis. This may increase the risk of uterine hemorrhage. Uterine prostaglandin increase in the hours before labor commences and by inhibition of prostaglandin synthesis, NSAIDs may impair the onset and normal progress of labor.

There may be increased bleeding tendency in both mother and child.

Lactation

Ketorolac has been detected in human milk at low concentrations and is CONTRAINDICATED in breastfeeding women (see ***Contraindications***).

Fertility

The use of ketorolac trometamol injection, as with any drug known to inhibit COX/prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive. In women who have difficulty conceiving or are undergoing investigation of infertility, withdrawal of ketorolac trometamol injection should be considered.

Children (< 16 years old)

The safety and effectiveness of ketorolac in children have not been established (see ***Contraindications***).

Elderly (≥ 65 years old)

Elderly patients are more susceptible to a variety of adverse reactions from NSAIDs; the incidence of these adverse reactions increases with dose and duration of treatment. In addition, these patients are less tolerant to ulceration and bleeding. As with any NSAID, caution should be exercised in treating the elderly (see ***Dosage and Administration***).

Renal Impairment

Ketorolac and its metabolites are eliminated by the kidneys, which in patients with reduced creatinine clearance will result in diminished plasma clearance of the drug (see ***Contraindications and Warnings and Precautions***).

UNDESIRABLE EFFECTS

The most common adverse effects with NSAIDs are GI, of which peptic ulcer, with or without bleeding, is the most severe. Fatalities have occurred, particularly in the elderly.

The most frequently reported adverse effects (1 to 13%) with ketorolac trometamol are somnolence, nausea, headache, vomiting, injection site pain, sweating, dizziness, and vasodilation.

Less common adverse effects (<1% of patients) include:

Blood and Lymphatic System*:* Anemia, agranulocytosis, aplastic anemia, bleeding at the operative site (rarely requiring blood transfusion), coagulation disorder, eosinophilia,epistaxis, hemolytic anemia, increased bleeding time, leukopenia, neutropenia, purpura, thrombocytopenia

Immune System*:* Anaphylactoid reactions, anaphylaxis, angioedema, asthma, hypotension, bronchospasm,flushing, laryngeal/lingual edema, rash

Metabolism and Nutrition: Anorexia, edema, excessive thirst, hyperkalemia, hypokalemia, hyponatremia, hypovolemia, increased appetite, weight gain

Psychiatric*:* Abnormal dreams, abnormal thinking, anxiety, depression, difficulty in concentration, euphoria, hallucinations, insomnia, nervousness, paranoid reaction, psychosis, psychotic reactions, stupor

Nervous System*:* Aseptic meningitis, asthenia, convulsions, extrapyramidal manifestations, functional disorders, hyperkinesia, nervousness, paresthesia, speech disorder, stimulation, tremors, vertigo

Special senses*:* Abnormal taste, diplopia, hearing loss, optic neuritis, retinal hemorrhage, tinnitus, visual disturbance (e.g., blurred vision)

Cardiovascular: Bradycardia, cardiac failure, chest pain, flushing, hematoma, hemorrhage, hypertension, hypotension, pallor, palpitation, postoperative wound hemorrhage, pulmonary embolus, syncope, tachycardia, ventricular tachycardia

Respiratory, Thoracic and Mediastinal*:* Asthma, dyspnea, epistaxis, hiccup, increased cough, pulmonary edema, rhinitis

Gastrointestinal*:* Abdominal pain/discomfort, anorexia, constipation, diarrhea, dry mouth, dyspepsia, eructation, esophagitis, exacerbation of colitis and Crohn's disease, feeling of GI fullness, flatulence, gastritis, GI bleeding, GI hemorrhage, GI pain, GI perforation, GI ulceration, hematemesis, melena, pancreatitis, peptic ulcer, rectal bleeding, sore throat, stomatitis, ulcerative stomatitis

Hepatic: Cholestatic jaundice, hepatitis, liver failure, liver function abnormalities

Skin and Subcutaneous Tissue*:* Bruising, bullous reactions (e.g., SJS and TEN or Lyell's syndrome), ecchymosis, erythema multiforme, exfoliative dermatitis, pruritus, rash (may be maculopapular), skin disorder, skin photosensitivity, subcutaneous hematoma, urticaria

Musculoskeletal*:* Back pain, myalgia, neck pain, twitching

General Disorders and Administration Site Conditions*:* Chills, fatigue, fever, infections, injection site reaction or pain, malaise, pain, tingling at the injection site

Urogenital/Reproductive*:* Acute renal failure, dysuria, flank pain (with or without hematuria and/or azotemia), glomerular nephritis, hematuria, hemolytic uremic syndrome, increased libido, increased urinary frequency, infertility, interstitial nephritis, nephritis, nephrotic syndrome, oliguria, polyuria, proteinuria, renal papillary necrosis, urinary retention, vaginitis

Investigations*:* Abnormal liver function tests, increased blood urea nitrogen (BUN) and creatinine, prolonged bleeding time

OVERDOSE AND TREATMENT

Daily doses of ketorolac 360 mg given IM/IV over an eight hour interval for five consecutive days caused abdominal pain and peptic ulcer which healed after discontinuation of dosing. There have been reports of metabolic acidosis following intentional overdosage.

Symptomatic and supportive care should be given to patients following an NSAID overdose. There are no specific antidotes.

Dialysis does not appear to be effective in removing the drug from circulation.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

STORAGE CONDITION

Keep out of sight and reach of children.
Store at temperatures not exceeding 30°C. Protect from light.

AVAILABILITY

Ketorolac Trometamol (KORTEZOR®) 30mg/mL ampule Solution for Injection (box of 10 ampules)

CAUTION: Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

Manufactured by AMHERST PARENTERALS, INC.
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UNILAB

Trusted Quality Healthcare

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