

120x340mm

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Kydor™ (Ketorolac Tromethamine)



COMPOSITION

Each 1mL ampoule contains:
Ketorolac Tromethamine 30mg

DESCRIPTION

Kydor (Ketorolac Tromethamine) is a member of the pyrrolo-pyrrole group of nonsteroidal anti-inflammatory drugs (NSAIDs).

MECHANISM OF ACTION

Ketorolac tromethamine is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits analgesic activity. The mechanism of action of ketorolac, like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition. The biological activity of ketorolac tromethamine is associated with the S-form. Ketorolac tromethamine possesses no sedative or anxiolytic properties. The peak analgesic effect of ketorolac occurs within 2 to 3 hours and is not statistically significantly different over the recommended dosage range of ketorolac. The greatest difference between large and small doses of ketorolac is in the duration of analgesia.

PHARMACOKINETICS

Ketorolac tromethamine is absorbed after intramuscular or oral doses. At physiological pH ketorolac tromethamine dissociates to form an anionic ketorolac molecule which is less hydrophilic than the tromethamine salt. Peak plasma concentrations of ketorolac occur within about 30 to 60 minutes; absorption after intramuscular injection may be slower than that after oral doses in some individuals. Ketorolac is over 99% bound to plasma proteins. It does not readily penetrate the blood brain barrier. Ketorolac crosses the placenta and small amounts of drug are distributed into breast milk. The terminal plasma half-life is about 4 to 6 hours but is about 6 to 7 hours in elderly and 9 to 10 hours in patients with renal dysfunction. The major metabolic pathway is glucuronic acid conjugation; there is some para hydroxylation. About 90% of the dose is excreted in urine as unchanged drug and conjugated and hydroxylated metabolites, the remainder excreted in the feces.

INDICATIONS

It is indicated for the short-term management of moderate to severe acute post-operative pain. Treatment should only be initiated in hospitals. The maximum duration of treatment is two days.

DOSAGE AND ADMINISTRATION

Initial Dosage

Ketorolac 30 mg/ml solution for injection is for administration by intramuscular or bolus intravenous injection. Bolus intravenous doses should be given over no less than 15 seconds. Ketorolac solution for injection should not be used for epidural or spinal administration.

The time to onset of analgesic effect following both IV and IM administration is 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.

Adults

The recommended initial dose of Ketorolac injection is 10mg, followed by 10 to 30 mg every four to six hours as required. In the initial post-operative period, Ketorolac solution for injection 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 50kg should not be exceeded. The maximum duration of treatment should not exceed two days. Reduce dosage in patients under 50kg.

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 solution for injection IM/IV, 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.

For patients receiving parenteral Ketorolac solution for injection, and who are converted to Ketorolac oral 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 40mg on the day the change of formulation is made. Patients should be converted to oral treatment as soon as possible.

Elder People

The older people 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 60mg should not be exceeded.

Children

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

Renal impairment

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

CONTRAINDICATIONS

It is contraindicated for:

- Ketorolac is contraindicated in patients with previously demonstrated hypersensitivity to Ketorolac, any of its excipients, or other NSAIDs and patients in whom aspirin or other prostaglandin synthesis inhibitors induce allergic reactions (severe anaphylactic-like reactions have been observed in such patients). Such reactions have included asthma, rhinitis, angioedema, or urticaria.
- Ketorolac is also contraindicated in
 - o those with a history of asthma
 - o children under 16 years of age.
- Ketorolac is contraindicated in patients with active or a history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy. Active or history of recurrent peptic ulcer / hemorrhage (two or more distinct episodes of proven ulceration or bleeding)
- As with other NSAIDs, Ketorolac is contraindicated in patients with severe heart failure, hepatic failure and renal failure.
- Ketorolac is contraindicated in patients with moderate or severe renal impairment (serum creatinine >160 µ mol/l) or inpatients at risk for renal failure due to volume depletion or dehydration.
- Ketorolac is contraindicated in pregnancy, labour, delivery or lactation.
- Ketorolac is contraindicated as prophylactic analgesia before surgery due to inhibition of platelet aggregation and is contraindicated intra-operatively because of the increased risk of bleeding.
- Ketorolac inhibits platelet function and is, therefore, contraindicated in patients with suspected or confirmed cerebrovascular bleeding, patients who have had operations with a high risk of hemorrhage or incomplete hemostasis and those at high risk of bleeding such as those with hemorrhagic diatheses, including coagulation disorders.
- It is also contraindicated in patients on anticoagulants, including warfarin and low dose heparin (2500 - 5000 units 12 hourly).
- Ketorolac is contraindicated in patients currently receiving ASA or other NSAIDs (including cyclooxygenase-2 selective inhibitors)
- Ketorolac Solution for injection is contraindicated for

neuraxial (epidural or intrathecal) administration due to its alcohol content.

- The combination of Ketorolac with xepentifylline is contraindicated.
- Concurrent treatment with ketorolac and probenecid or lithium salts is contraindicated.
- Ketorolac is contraindicated in patients with the complete or partial syndrome of nasal polyps, angioedema or bronchospasm.

INCOMPATIBILITIES

Ketorolac solution for injection 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. It is compatible with 0.9% normal saline and 5% dextrose solution.

WARNING AND PRECAUTIONS

- Ketorolac may be associated with a high risk of serious gastrointestinal toxicity, relative to some other NSAIDs, especially when used outside the licensed indications and/or for prolonged periods. Physicians should be aware that in some patient's pain relief may not occur until upwards of 30 minutes after IV or IM administration. The use of Ketorolac with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.
- Gastrointestinal bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs including ketorolac therapy, at any time during treatment, with or without warning symptoms or a previous history of serious GI events. The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation which may be fatal. Debilitated patients seem to tolerate ulceration or bleeding less well than others. Most of the fatal gastrointestinal events associated with non-steroidal anti-inflammatory drugs occurred in the elderly and/or debilitated patients. The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, including Ketorolac IV, inpatients with a history of ulcer, particularly if complicated with hemorrhage or perforation, and in the elderly. The risk of clinically serious gastrointestinal bleeding is dose dependent. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk. This age related risk of gastrointestinal bleeding and perforation is common to all NSAIDs. Compared to young adults, the elderly have an increased plasma half-life and reduced plasma clearance of Ketorolac.
- NSAIDs should be given with care to patients with a history of inflammatory bowel disease, (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated. Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment. When GI bleeding or ulceration occurs in patients receiving Ketorolac IV, treatment should be withheld.
- Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin.
- Use in patients taking anticoagulants such as warfarin is contraindicated.
- As with other NSAIDs the incidence and severity of gastrointestinal complications may increase with increasing dose and duration of treatment with Ketorolac IV. The risk of clinically serious gastrointestinal bleeding is dose dependent. This is particularly true in elderly patients who receive an average daily dose greater than 60 mg/day of Ketorolac IV. A history of peptic ulcer disease increases the possibility of developing serious gastrointestinal complications during Ketorolac therapy.
- Patients with coagulation disorders should not receive Ketorolac solution for injection. Patients on anticoagulation therapy may be at increased risk of bleeding if given Ketorolac solution for injection concurrently. The concomitant use of Ketorolac and prophylactic low dose heparin (2500-5000 units 12-hourly) and dextran has not been studied extensively and may also be associated with an increased risk of bleeding. Patients already on anticoagulants or who require low-dose heparin should not receive ketorolac. Patients who are receiving other drug therapy that interferes with hemostasis should be carefully observed if Ketorolac solution for injection is administered. 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. 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, resection of the prostate or tonsillectomy. Hematomas and other signs of wound hemorrhage and epistaxis have been reported with the use of Ketorolac solution for injection.
- Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk for these reactions early in the course of therapy: the onset of the reactions occurring in the majority of cases within the first month of treatment. Ketorolac solution for injection should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
- In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.
- Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with NSAID therapy. Fluid retention, hypertension and peripheral oedema has been observed in some patients taking NSAIDs including Ketorolac and it should therefore be used with caution in patients with cardiac decompensation, hypertension or similar conditions.
- Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy. Data suggests that use of coxibs and some NSAIDs (particularly at high doses) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Although ketorolac has not shown to increase thrombotic events such as myocardial infarction, there are insufficient data to exclude such a risk for Ketorolac.
- Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with Ketorolac after careful consideration. Similar considerations should be made before initiating treatment of patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidemia, diabetes mellitus and smoking).
- Caution should be observed in patients with conditions leading to a reduction in blood volume and/or renal blood flow, where renal prostaglandins have a supportive role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose dependent reduction in renal prostaglandin formation and may precipitate overt renal failure. Patients at greatest risk of this reaction are those who are volume depleted because of blood loss or severe dehydration, patients with impaired renal function, heart failure, liver dysfunction, the elderly and those taking diuretics. Renal function should be monitored in these patients. Discontinuation of NSAID therapy is typically followed by recovery to the pre-treatment state. Inadequate fluid/blood replacement during surgery, leading to hypovolemia, may lead to renal dysfunction which could be exacerbated when Ketorolac solution for injection is administered. Therefore, volume depletion should be corrected, and close monitoring of serum urea and creatinine and urine output is recommended until the patient is normovolaemic. In patients on renal dialysis, ketorolac clearance was reduced to approximately half the normal rate and terminal half-life increased approximately three fold.
- As with other NSAIDs Ketorolac should be used with caution in patients with impaired renal function or a history of kidney disease because it is a potent inhibitor of prostaglandin synthesis. Caution should be observed as renal toxicity has been seen with Ketorolac and other NSAIDs in patients with conditions leading to a reduction in blood volume and/or renal blood flow where renal prostaglandins have a supportive role in the maintenance of renal perfusion. In these patients' administration of Ketorolac or other NSAIDs may cause a dose dependent reduction in renal prostaglandin formation and may precipitate overt renal decompensation or failure.

Patients at greatest risk of this reaction are those with impaired renal function, hypovolemia, heart failure, liver dysfunction, those taking diuretics and the elderly. Discontinuation of Ketorolac or other non-steroidal anti-inflammatory therapy is usually followed by recovery to the pre-treatment 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.
- Anaphylactic (anaphylactoid) reactions (including, but not limited to, anaphylaxis, bronchospasm, flushing, rash, hypotension, laryngeal oedema and angioedema) may occur in patients with or without a history of hypersensitivity to aspirin other NSAIDs or Ketorolac IV. These may also occur in individuals with a history of angioedema, bronchospastic reactivity (e.g. asthma) and nasal polyps. Anaphylactoid reactions, like anaphylaxis, may have a fatal outcome. Therefore, Ketorolac should be used with caution in patients with a history of asthma and in patients with the complete or partial syndrome of nasal polyps, angioedema and bronchospasm.
- The use of Ketorolac injection, as with any drug known to inhibit cyclooxygenase / 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 fertility, withdrawal of Ketorolac injection should be considered.
- Fluid retention, hypertension and oedema have been reported with the use of Ketorolac and it should therefore be used with caution in patients with cardiac decompensation, hypertension or similar conditions.
- Caution is advised when methotrexate is administered concurrently since some prostaglandin synthesis-inhibiting drugs have been reported to reduce the clearance of methotrexate, and thus possibly enhance its toxicity.

ADVERSE REACTIONS

The reported adverse effects of ketorolac are: peptic ulcers, ulcers, perforation or GI bleeding, nausea, vomiting, diarrhea, constipation, dyspepsia, abdominal pain, abdominal discomfort, melana, hematemesis, stomatitis, ulcerative stomatitis, eructation, flatulence, esophagitis, gastrointestinal ulceration, rectal bleeding, pancreatitis, dry mouth, fullness, exacerbation of colitis, Crohn's disease, meningitis aseptic. (especially in patients with existing auto immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation, thrombocytopenia, purpura, neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia, anaphylaxis, anaphylactoid reactions, anaphylactoid reactions like anaphylaxis, hypersensitivity reactions such as flushing, bronchospasm, rash, hypotension, laryngeal oedema, angioedema, bronchospastic reactivity (e.g. asthma and nasal polyps), anorexia, hyperkalemia, hyponatremia, abnormal thinking, depression, insomnia, anxiety, nervousness, psychotic reactions, abnormal dreams, hallucinations, euphoria, concentration ability impaired, drowsiness, confusion, stimulation, headache, dizziness, convulsions, paresthesia, hyperkinesia, taste abnormality, abnormal vision, visual disturbances, optic neuritis, tinnitus, hearing loss, vertigo, acute renal failure, increased urinary frequency, interstitial nephritis, nephrotic syndrome, urinary retention, oliguria, hemolytic uremic syndrome, flank pain (with or without hematuria azotemia), palpitations, bradycardia, cardiac failure, hypertension, hypotension, hematoma, flushing, pallor, postoperative wound hemorrhage, arterial thrombotic events, female infertility, asthma, dyspnea, pulmonary oedema, epistaxis, hepatitis, cholestatic jaundice, liver failure, exfoliative dermatitis, maculopapular rash, pruritus, urticaria, purpura, angioedema, sweating, bullous reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, skin photosensitivity, myalgia, functional disorder, excessive thirst, asthenia, oedema, injection site reactions , pain, fever, chest pain, malaise, fatigue weight gain, bleeding time prolonged, serum urea increased, creatinine increased and abnormal liver function tests.

DRUG INTERACTIONS

- Ketorolac solution for injection should not be used with other ASA or other NSAIDs including cyclooxygenase-2 selective inhibitors as the risk of inducing serious NSAID-related adverse events may be increased.
- Ketorolac inhibits platelet aggregation, reduces thromboxane concentrations and prolongs bleeding time. Unlike the prolonged effects from aspirin, platelet function returns to normal within 24-48 hours after Ketorolac is discontinued.
- Ketorolac injection is contraindicated in combination with anticoagulants, such as warfarin since co-administration of NSAIDs and anticoagulants may cause an enhanced anticoagulant effect.
- The concurrent use of Ketorolac and therapy that affects hemostasis, including therapeutic doses of anticoagulation therapy (warfarin)/prophylactic low-dose heparin (2500-5000 units 12-hourly) and dextran may be associated with an increased risk of bleeding.
- Inhibition of renal lithium clearance, leading to an increase in plasma lithium concentration, has been reported with some prostaglandin synthesis inhibiting drugs. Cases of increased lithium plasma concentrations during Ketorolac therapy have been reported.
- Probenecid should not be administered concurrently with ketorolac because of increases in ketorolac plasma concentrations and half-life.
- NSAIDs should not be used for eight to twelve days after mifepristone administration as NSAIDs can reduce the effects of mifepristone.
- As with all NSAIDs, caution should be taken when co-administering with corticosteroids because of the increased risk of gastro-intestinal ulceration or bleeding.
- There is an increased risk of gastrointestinal bleeding, when antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs) are combined with NSAIDs.
- When ketorolac is administered concurrently with xepentifylline, there is an increased tendency to bleeding.
- Some prostaglandin synthesis inhibiting drugs have been reported to reduce the clearance of methotrexate, and thus possibly enhance its toxicity.
- Ketorolac tromethamine does not alter digoxin protein binding. Therapeutic concentrations of digoxin, warfarin, ibuprofen, naproxen, piroxicam, acetaminophen, phenytoin and tolbutamide did not alter ketorolac protein binding.
- Ketorolac reduced the diuretic response to furosemide, so particular care should be taken in patients with cardiac decompensation.
- Co-administration with diuretics can lead to a reduced diuretic effect and increase the risk of nephrotoxicity of NSAIDs.
- As with all NSAIDs caution is advised when ciclosporin is co-administered because of the increased risk of nephrotoxicity.
- There is a possible risk of nephrotoxicity when NSAIDs are given with tacrolimus.
- NSAIDs may reduce the effect of diuretics and antihypertensive medicinal products. The risk of acute renal insufficiency, which is usually reversible, may be increased in some patients with compromised renal function (e.g. dehydrated patients or elderly patients) when ACE inhibitors and/or angiotensin II receptor antagonists are combined with NSAIDs. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately titrated and consideration should be given to monitoring renal function after initiation of concomitant therapy, and periodically thereafter.
- NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels when co-administered with cardiac glycosides.
- Ketorolac has been shown to reduce the need for concomitant opioid analgesia when it is given for the relief of postoperative pain.
- Oral administration of Ketorolac Tablets after a high-fat meal resulted in decreased peak and delayed time to peak concentrations of ketorolac by about 1 hour. Antacids did not affect the extent of absorption.
- NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.
- NSAIDs given with zidovudine increase the risk of hematological toxicity. There is evidence of an increased risk of hemarthroses and hematoma in HIV (+) hemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

USE IN SPECIFIC POPULATIONS

Pregnancy

The fetal cardiovascular system (risk of closure of the ductus arteriosus) ketorolac is contraindicated during pregnancy, labour or delivery. The safety of Ketorolac injection during human pregnancy has not been established.

Congenital abnormalities have been reported in association with NSAID administration in man, however these are low in frequency and do not follow any discernible pattern. Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/ fetal development.

An increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy.

During pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension)
 - renal dysfunction, which may progress to renal failure with oligo hydramnios;
- The mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
 - inhibition of uterine contractions resulting in delayed or prolonged labour

Labour and Delivery

Ketorolac is contraindicated in labour and delivery because, through its prostaglandin synthesis inhibitory effect it may adversely affect fetal circulation and inhibit uterine contractions, thus increasing the risk of uterine hemorrhage. There may be an increased bleeding tendency in both mother and child.

Nursing Mothers:

Ketorolac and its metabolites have been shown to pass into the fetus and milk of animals. Ketorolac has been detected in human milk at low concentrations, therefore ketorolac is contraindicated in mothers who are breast feeding.

Pediatric Use:

Ketorolac tablets are not recommended for use in children. Ketorolac given parenterally is not recommended in children younger than 2 years of age.

Geriatric Use

Because ketorolac may be cleared more slowly by the elderly, who are also more sensitive to the dose related adverse effects of NSAIDs extreme caution, reduced dosages and careful clinical monitoring must be used when treating the elderly with ketorolac.

Renal Impairment

Since ketorolac and its metabolites are excreted primarily by the kidney, patients with moderate to severe impairment of renal function (serum creatinine greater than 160 micro mol/l) should not receive Ketorolac injection. Patients with lesser renal impairment should receive a reduced dose of ketorolac (not exceeding 60mg/day IM or IV) and their renal status should be closely monitored.

Hepatic Impairment

Patients with impaired hepatic function from cirrhosis do not have any clinically important changes in ketorolac clearance or terminal half-life. Borderline elevations of one or more liver function tests may occur. These abnormalities may be transient, may remain unchanged, or may progress with continued therapy. If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur, Ketorolac injection should be discontinued.

Drug Abuse and Dependence

Ketorolac is devoid of addictive potential. No withdrawal symptoms have been observed following abrupt discontinuation of Ketorolac IV.

Effects on ability to drive and use machine

Some patients may experience dizziness, drowsiness, fatigue, visual disturbances, headache, vertigo, insomnia or depression with the use of Ketorolac injection. If patients experience these, or other similar undesirable effects, patients should not drive or operate machinery.

OVERDOSAGE

Symptoms and signs

Overdoses of Ketorolac have been associated with abdominal pain, nausea, vomiting, peptic ulcer, renal dysfunction, hyperventilation, and erosive gastritis which have resolved after discontinuation of dosing. Gastrointestinal bleeding, hypertension, acute renal failure, respiratory depression and coma, headache, epigastric pain, disorientation, excitation, drowsiness, dizziness, tinnitus, fainting, diarrhea, convulsions (occasionally), anaphylactoid reactions may occur following an overdose.

Treatment

Patients should be managed by symptomatic and supportive care following NSAIDs overdose. There are no specific antidotes. Dialysis does not significantly clear ketorolac from the blood stream. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least four hours after ingestion of potentially toxic amounts. Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

DOSAGE AND INSTRUCTIONS

To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION

Kydor 30mg IM/IV Injection

Alu. PVC Blister Pack of 1mL x 5's.



خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخے کے مطابق ہی دوا فروخت اور استعمال کی جائے۔

بچوں کی پہنچنے سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔

خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

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