פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

אוגוסט 2017

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של **Ketalar Injection 10mg/ml ו- Ketalar Injection 50mg/ml:**
קו תחתי משמעו תוספת טקסט, קו חוצה משמעו מחיקת טקסט, הדגשה משמעה החמרה.

<u>הרכב וחוזק:</u>

Each ml contains 10 mg or 50 mg ketamine (as hydrochloride).

<u>התוויה:</u>

As the sole anaesthetic agent for diagnostic and surgical procedures. When used by intravenous or intramuscular injection, Ketalar is best suited for short procedures. With additional doses, or by intravenous infusion, Ketalar can be used for longer procedures. If skeletal muscle relaxation is desired a muscle relaxant should be used and respiration should be supported.
For the induction of anaesthesia prior to the administration of other general anaesthetic agents.
To supplement other anaesthetic agents.
Specific areas of application or types of procedure: When the intramuscular route of administration is preferred.
Debridement, painful dressings and skin grafting in burned patients as well as other superficial surgical procedures.
Neurodiagnostic procedures such as pneumoencephalograms, ventriculograms, myelograms and lumbar punctures.
Diagnostic and operative procedures of the eye, ear, nose and mouth including dental extractions. (Note: eye movement may persist during ophthalmological procedures).
Anaesthesia in poor-risk patients with depression of vital functions or where depression of vital functions must be avoided if at all possible.
Orthopaedic procedures such as closed reduction, manipulation femoral pinning, amputations and biopsies.
Sigmoidoscopy and minor surgery of the anus and rectum, circumcision and pilonidal sinus.
Cardiac catheterization procedures.
Caesarean section: as an induction agent in the absence of elevated blood pressure.
Anaesthesia in the asthmatic patient, either to minimise the risk of an attack of bronchospasm developing or in the presence of bronchospasm where anaesthesia cannot be delayed.

<u>להלן העדכונים העיקריים בעלון לרופא:</u>

Contraindications

<u>Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.</u>
Ketalar is contra-indicated in persons in whom an elevation of blood pressure would constitute a serious hazard (see section 4.8). ~~Ketamine hydrochloride is contraindicated in patients who have shown hypersensitivity to the drug or its components~~ Ketalar should not be used in patients with eclampsia or pre-eclampsia, severe coronary or myocardial disease, cerebrovascular accident or cerebral trauma.

Special warnings and percaution for use

Respiratory depression may occur with overdosage of Ketalar, in which case supportive ventilation should be employed. Mechanical support of respiration is preferred to the administration of analeptics.

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Use with caution in patients with globe injuries and increased intraocular pressure (e.g. glaucoma) because the pressure may increase significantly after a single dose of ketamine.

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<u>Long-Term Use</u>

Cases of cystitis including haemorrhagic cystitis have been reported in patients being given ketamine on a long term basis. This adverse reaction develops in patients receiving long term ketamine treatment after a time ranging from 1 month to several years. **Ketamine is not indicated nor recommended for long term use.** Hepatotoxicity has also been reported in patients with extended use (> 3 days).

Drug Abuse and Dependence
Ketalar has been reported as being a drug of abuse. Reports suggest that ketamine produces a variety of symptoms including, but not limited to, flashbacks, hallucinations, dysphoria, anxiety, insomnia, or disorientation. Cases of cystitis including haemorrhagic cystitis and cases of hepatotoxicity have also been reported. If used on a daily basis for a few weeks, dependence and tolerance may develop, particularly in individuals with a history of drug abuse and dependence. Therefore the use of Ketalar should be closely supervised and it should be prescribed and administered with caution.

Interaction with other medicinal products and other of interaction
Ketalar is chemically incompatible with barbiturates and diazepam because of precipitate formation. Therefore, these should not be mixed in the same syringe or infusion fluid.
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Fertility, Pregnancy and Lactation
Pregnancy
Ketalar crosses the placenta. This should be borne in mind during operative obstetric procedures in pregnancy. No controlled clinical studies in pregnancy have been conducted. The use in pregnancy has not been established, and such use is not recommended, with the exception of administration during surgery for abdominal delivery or vaginal delivery.

Some neonates exposed to ketamine at maternal intravenous doses ≥ 1.5 mg/kg during delivery have experienced respiratory depression and low Apgar scores requiring newborn resuscitation.

Marked increases in maternal blood pressure and uterine tone have been observed at intravenous doses greater than 2 mg/kg.

Data are lacking for intramuscular injection and maintenance infusion of ketamine in the parturient population, and recommendations cannot be made. Available data are presented in Section 5.2.
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Effets on Aability to Drive and Use Machines
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This medicine can impair cognitive function and can affect a patient's ability to drive safely.
When prescribing this medicine, patients should be told:
• The medicine is likely to affect your ability to drive
• Do not drive until you know how the medicine affects you
• It is an offence to drive while under the influence of this medicine
• However, you would not be committing an offence (called 'statutory defence') if:
  - o The medicine has been prescribed to treat a medical or dental problem and
  - o You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
  - o It was not affecting your ability to drive safely

Overdosage
…
Ketalar has a wide margin of safety; several instances of unintentional administration of overdoses of Ketalar (up to 10 times that usually required) have been followed by prolonged but complete recovery.

העלון לרופא נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:
http://www.health.gov.il/units/pharmacy/trufot/index.asp
לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ
שנקר 9, ת.ד. 12133
הרצליה פיתוח, 46725.
בברכה,

אורטל עבודי
רוקחת ממונה