



אוקטובר 2018

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא (עלון לצרכן במתכונת עלון לרופא) של התכשירים:

Ketalar injection 10mg/ml

Ketalar 50mg/ml injection

המרכיב הפעיל:

Ketamine (as hydrochloride) 10mg/mL

Ketamine (as hydrochloride) 50mg/ml

Indicated for:

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.

Caesarian 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.

להלן העדכונים העיקריים בעלון לרופא:

4.5 Interaction with other medicinal products and other forms of interaction

Prolonged recovery time may occur if barbiturates and/or narcotics are used concurrently with Ketalar®.

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.

Diazepam is known to increase the half-life of ketamine and prolongs its pharmacodynamic effects. Dose adjustments may therefore be needed.

Ketamine may potentiate the neuromuscular blocking effects of atracurium and tubocurarine including respiratory depression with apnoea.

The use of halogenated anaesthetics concomitantly with ketamine can lengthen the elimination half-life of ketamine and delay recovery from anaesthesia. Concurrent use of ketamine (especially in high

doses or when rapidly administered) with halogenated anaesthetics can increase the risk of developing bradycardia, hypotension or decreased cardiac output.

The use of ketamine with other central nervous system (CNS) depressants (e.g. ethanol, phenothiazines, sedating H₁ – blockers or skeletal muscle relaxants) can potentiate CNS depression and/or increase risk of developing respiratory depression. Reduced doses of ketamine may be required with concurrent administration of other anxiolytics, sedatives and hypnotics.

Ketamine has been reported to antagonise the hypnotic effect of thiopental.

Patients taking thyroid hormones have an increased risk of developing hypertension and tachycardia when given ketamine.

Concomitant use of antihypertensive agents and ketamine increases the risk of developing hypotension.

Sympathomimetics (directly or indirectly acting) and vasopressin may enhance the sympathomimetic effects of ketamine.

Concomitant use with ergometrine may lead to an increase in blood pressure.

When ketamine and theophylline or aminophylline are given concurrently, a clinically significant reduction in the seizure threshold may be ~~is~~ observed. Unpredictable extensor-type seizures have been reported with concurrent administration of these agents.

Drugs that inhibit CYP3A4 enzyme activity generally decrease hepatic clearance, resulting in increased plasma concentration of CYP3A4 substrate medications, such as ketamine. Coadministration of ketamine with drugs that inhibit CYP3A4 enzyme may require a decrease in ketamine dosage to achieve the desired clinical outcome.

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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:
<https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h>

לחילופין, לקבלת עלונים מלאים מודפסים ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ
שנקר 9, ת.ד. 12133
הרצליה פיתוח, 46725.

בברכה,
אורטל עבודי
רוקחת ממונה