



פיזר 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

מרץ 2020

רופא/ה, רוקח/ת נכבד/ה,

חברת פיזר פי אף אי ישראל בע"מ, מבקשת להודיעכם על עדכון בעלון לרופא של התכשירים:

Ketalar® Injection 10 mg/ml  
Ketalar® 50 mg/ml Injection

הודעה זו מפרטת את העדכונים המהווים החמרה במידע הבטיחותי בלבד, למידע מלא יש לעיין בעלון.  
העלון לרופא מפורסם במאגר התרופות שבמשרד הבריאות, וניתן לקבלו מודפסים על ידי פניה לבעל הרישום:  
חברת פיזר פי אף אי פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133, הרצליה פיתוח, 46725.

#### שם התכשיר:

Ketalar® Injection 10 mg/ml  
Ketalar® 50 mg/ml Injection

#### הרכב וחוזק:

Each 1 ml of solution contains:

Ketalar® Injection 10mg/ml: ketamine (as hydrochloride) equivalent to 10 mg ketamine base per ml  
Or

Ketalar® 50mg/ml Injection: ketamine (as hydrochloride) equivalent to 50 mg ketamine base per ml.

#### התוויה מאושרת:

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 procedures:

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 movements 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 reductions, manipulations, 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 risks of an attack of bronchospasm developing, or in the presence of bronchospasm where anaesthesia cannot be delayed.

**להלן עדכוני הבטיחות בעלון לרופא (מסומנים בצהוב):**

#### **4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

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##### Long-Term Use

Cases of cystitis, including haemorrhagic cystitis, acute kidney injury, hydronephrosis, and ureteral disorders have been reported in patients being given ketamine on a long term basis, especially in the setting of ketamine abuse. These adverse reactions develop 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).

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