

As the sole anaesthetic agent for diagnostic and surgical procedures. When used by intravenous or intramuscular injection, Ketamine-hameln is best suited for short procedures. With additional doses, or by intravenous infusion, Ketamine-hameln 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.

מרכיב פעיל: KETAMINE (AS HYDROCHLORIDE) 50 MG/ML

צורת המתן של התכשיר: Solution for Injection or Infusion

עדכון בעלון לרופא, המהווה החמרה, נעשה בסעיפים הבאים (מודגש בצהוב):
בעלון נעשו עדכונים נוספים על העדכונים המפורטים כאן.

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 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).

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4.6 Fertility, pregnancy and lactation

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Lactation

The safe use of ketamine during lactation has not been established, and such use is not recommended.

Studies in animals have shown reproductive toxicity (see section 5.3).

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות:

<https://data.health.gov.il/drugs/index.html#!/byDrug>

ניתן לקבל עלון מודפס ע"י פנייה לבעל הרישום: חברת פרמה מדיס בע"מ, רחוב פיירברג 4, ת.ד. 2820, חולון.

בברכה,

אבנר דור

רוקח ממונה