



MAL20126022ACZ

Midazolam Kalceks

5 mg/ml solution for injection/infusion

Midazolam is a derivative of the imidazobenzodiazepine group. The free base is a lipophilic substance and has a low solubility in water.

The basic nitrogen in position 2 of the imidazobenzodiazepine ring enables midazolam to form water-soluble salts with acids, producing a stable and well-tolerated solution for injection or infusion.

The pharmacological effect of midazolam is characterised by short duration because of a rapid metabolic transformation over a short time. Midazolam has a potent sedative and sleep-inducing effect. Furthermore, it has the effect of relieving anxiety and convulsions and of relaxing muscles.

After intramuscular or intravenous administration, anterograde amnesia of short duration occurs; the patient does not remember events occurring at the time of the substance's maximal activity.

Approved:

- By the Food and Drug Administration (FDA) on December 20, 1985;
- In Europe (Germany) on December 22, 1998.

Indications:

Midazolam Kalceks is a short-acting sleep-inducing drug that is indicated as follows:

In adults

- CONSCIOUS SEDATION before or during diagnostic or therapeutic procedures with or without local anaesthesia
- ANAESTHESIA
 - Premedication before induction of anaesthesia
 - Induction of anaesthesia
 - As a sedative component in combined anaesthesia
- SEDATION IN INTENSIVE CARE UNITS

In paediatric

- CONSCIOUS SEDATION before or during diagnostic or therapeutic procedures with or without local anaesthesia
- ANAESTHESIA
 - Premedication before induction of anaesthesia
- SEDATION IN INTENSIVE CARE UNITS

Route of administration:

Ampoules for intravenous infusion, intravenous injection, intramuscular and rectal administration. For instructions on dilution of the medicinal product before administration, see package insert.

Midazolam advantages:

- Midazolam's short duration, cardiorespiratory stability, anxiolytic and amnesic properties makes it the drug of choice for moderate sedation.
- Midazolam is rapidly and fully absorbed from the muscle tissue. The peak plasma concentration is reached within 30 minutes. The absolute bioavailability after intramuscular administration is over 90%.
- Midazolam is rapidly absorbed after rectal administration. The peak plasma concentration is reached within approximately 30 minutes. The absolute bioavailability is approximately 50%.
- Midazolam is mostly eliminated through the kidneys (60 - 80% of the dose injected) and is recovered as glucuronide-conjugated alpha-hydroxymidazolam. The elimination half-life in patients with chronic renal failure is similar to that in healthy volunteers, thus midazolam is safe for use in patients with renal impairment.

Midazolam Kalceks 5 mg/ml solution for injection/infusion available:

Type 1 colourless glass ampoules with one point cut containing 1 ml or 3 ml solution.

Product shelf life - 30 months

Special precautions for storage:

Store below 30 °C.
Keep the ampoules in the outer carton in order to protect from light. Do not freeze.

Pack sizes:

- 10 ampoules of 1 ml.
- 10 ampoules of 3 ml.

Refer package insert for further information.

Distributed by:

EUCOGEN

Eucogen Sdn. Bhd. 201401017699 (1093786-A)
6A, Jalan Sungai Burung U 32/U, Bukit Rimau, 40460 Shah Alam, Selangor.
Tel: +603 5131 1997 Fax: +603 5120 1639

Controlled Medicine

Manufactured by:
HBM Pharma s.r.o.
Martin, Slovakia

Strictly for healthcare professionals use only.
MY-0292021


Kalceks