



Black (60%)

PANTONE: 1375 C 3125 C 286 C 716 C Black

Place for data matrix code

Transparent perforate anti-tamper device.

In some cases internal codes of printing-house may be indicated



Midazolam Kalceks 5 mg/ml
 solution for injection/infusion
 Midazolam
 15 mg/3 ml
 10 ampoules of 3 ml
 Kalceks

1 ml of solution contains 5 mg of midazolam. Each ampoule with 1 ml of solution contains 5 mg of midazolam. Excipients: hydrochloric acid concentrated, sodium chloride, sodium hydroxide, water for injections. Medicinal product subject to medical prescription. Controlled Medicine. Ubat Terkawal. Read the package insert before use. Store below 30 °C. Keep the ampoules in the outer carton in order to protect from light. Do not freeze.
 Shelf life after dilution
 Chemical and physical in-use stability has been demonstrated 40 hours at 25 °C and 3 days at 2-8 °C temperature with following infusion solutions: sodium chloride 0.9 %, glucose 5 % and 10 % and Ringers's solution. From a microbiological point of view, the dilutions should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions. Keep out of the sight and reach of children. Jauhkan dari pandangan dan jangkauan kanak-kanak.

Manufactured by:
 HBM Pharma s.r.o.
 Martin, Slovakia
 MAL20126022ACZ
 BRU22113265P

Product Registration Holder:
 Eucogen Sdn Bhd
 6A, Jalan Sungai Burung U
 32/U, Bukit Rimau, 40460 Shah
 Alam, Selangor, Malaysia

Brunei Darussalam Product Licence Holder:
 Nova Borneo Company Sdn Bhd
 Unit 4GF Bangunan Zainuddin & Azizah,
 Simpang 501
 Jalan Tutong, Kg Telanai, Brunei-Muara Ba2312



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Routes of administration:
intramuscular, intravenous, rectal.

10 ampoules of 3 ml



Lot
 MFG
 EXP

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 Midazolam
 15 mg/3 ml
 10 ampoules of 3 ml
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Place for AS Kalceks internal code

Place for manufacturer internal code

Place for data matrix code