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KETABEL 100 MG/ML SOLUTION FOR INJECTION

Authorised

- Ketamine hydrochloride

Product identification

Medicine name:
KETABEL 100 MG/ML SOLUTION FOR INJECTION

Active substance:
Ketamine hydrochloride

Target species:
Cattle
Pig
Rat
Guinea pig
Rabbit
Cat
Sheep
Goat
Dog
Horse
Hamster
Mouse

Route of administration:
Intramuscular use

Intravenous use
Intraperitoneal use

Product details

Active substance and strength:
Ketamine hydrochloride
115.34 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 1 day
  - Milk. 0 day
- **Pig**
  - Meat and offal. 1 day
- **Sheep**
  - Meat and offal. 1 day
  - Milk. 0 day
- **Goat**
  - Meat and offal. 1 day
  - Milk. 0 day

Intravenous use:

- **Cattle**

- Meat and offal. 1 day
- Milk. 0 day

- **Horse**
  - Meat and offal. 1 day
  - Milk. 0 day

- **Sheep**
  - Meat and offal. 1 day
  - Milk. 0 day

- **Goat**
  - Meat and offal. 1 day
  - Milk. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN01AX03

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

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Authorisation status:
Valid

Authorised in:
Romania

Available in:
Romania

Package description:
Carton with 1 vial of 10 mL
Carton with 10 vials of 25 mL
Carton with 1 vial of 25 mL
Carton with 10 vials of 10 mL

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Bela-Pharm GmbH & Co. KG

Marketing authorisation date:
14/09/2020

Manufacturing sites for batch release:
Bela-Pharm GmbH & Co. KG

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
250129

Date of authorisation status change:
27/10/2025

Reference member state:
France

Procedure number:
FR/V/0338/001

Concerned member states:
Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia Finland Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

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Documents

Combined File of all Documents

English (PDF)
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