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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:
Denmark

Available in:
Denmark

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:
25/04/2022

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

Responsible authority:
Danish Medicines Agency

Authorisation number:
66501

Date of authorisation status change:
25/04/2022

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)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Combined File of all Documents

eu-puar-frv0338001-mr-rpe665-en.pdf