KETABEL 100 MG/ML SOLUTION FOR INJECTION

Authorised

- Ketamine hydrochloride

Product identification

Medicine name:
KETABEL 100 MG/ML SOLUTION FOR INJECTION
Ketabel 100 mg/ml oldatos injekció kutyák, macskák, szarvasmarhák, juhok, kecskék, lovak, sertések és laboratóriumi álla

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

Authorisation status:
Valid

Authorised in:
Hungary

Available in:
Hungary

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:
2/07/2020

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

Responsible authority:
Directorate Of Veterinary Medicinal Products

Authorisation number:
4192/X/20 NÉBIH ÁTI

Date of authorisation status change:
2/07/2020

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