

# 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 soluzione iniettabile

### 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

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## Product details

### Active substance and strength:

Ketamine hydrochloride  
115.34 milligram(s) / 1.00 millilitre(s)

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### Pharmaceutical form:

Solution for injection

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### Withdrawal period by route of administration:

#### Intramuscular use:

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##### Cattle

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

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##### Pig

- Meat and offal. 1 day

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##### Sheep

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

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##### Goat

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

#### Intravenous use:

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**Cattle**

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

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**Horse**

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

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**Sheep**

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

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**Goat**

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

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QN01AX03

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**Legal status of supply:**

Veterinary medicinal product not subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Italy

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**Available in:**

Italy

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**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

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Bela-Pharm GmbH & Co. KG

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**Marketing authorisation date:**

3/10/2022

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**Manufacturing sites for batch release:**

Bela-Pharm GmbH & Co. KG

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**Responsible authority:**

Ministry Of Health

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**Authorisation number:**

105638

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**Date of authorisation status change:**

28/09/2022

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**Reference member state:**

France

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**Procedure number:**

FR/V/0338/001

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**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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To consult adverse reactions on veterinary medicinal products please go to [www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Combined File of all Documents

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