

# KETEXX 100 MG/ML SOLUTION FOR INJECTION

Authorised

- Ketamine hydrochloride

## Product identification

### Medicine name:

KETEXX 100 MG/ML SOLUTION FOR INJECTION

Ketexx 100 mg/ml ενέσιμο διάλυμα

### Active substance:

Ketamine hydrochloride

### Target species:

Cattle

Rat

Mouse

Hamster

Guinea pig

Rabbit (exclusively kept as pet)

Cat

Horse

Dog

Sheep

Goat

### Route of administration:

Intramuscular use

Intravenous use  
Intraperitoneal use

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## Product details

### **Active substance and strength:**

Ketamine hydrochloride  
115.30 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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##### **Rabbit (exclusively kept as pet)**

- All relevant tissues. no withdrawal period

Not authorised for use in rabbits for human consumption.

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##### **Horse**

- 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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**Rabbit (exclusively kept as pet)**

- All relevant tissues. no withdrawal period

Not authorised for use in rabbits for human consumption.

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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

**Intraperitoneal use:**

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**Rabbit (exclusively kept as pet)**

- All relevant tissues. no withdrawal period

Not authorised for use in rabbits for human consumption.

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

QN01AX03

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Cyprus

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**Package description:**

Polystyrene box holding 15 vials of 50 ml  
Carton box holding 1 vial of 10 ml  
Carton box holding 1 vial of 20 ml  
Carton box holding 1 vial of 50 ml  
Carton box holding 5 vials of 10 ml  
Carton box holding 5 vials of 20 ml  
Carton box holding 5 vials of 50 ml  
Polystyrene box holding 35 vials of 10 ml  
Polystyrene box holding 28 vials of 20 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:**

Alfasan Nederland B.V.

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**Marketing authorisation date:**

29/05/2022

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**Manufacturing sites for batch release:**

Alfasan Nederland B.V.

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**Responsible authority:**

Veterinary Services, Ministry Of Agriculture, Natural Resources And Environment

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**Authorisation number:**

CY00855V

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**Date of authorisation status change:**

29/05/2022

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**Reference member state:**

France

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**Procedure number:**

FR/V/0435/001

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**Concerned member states:**

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland  
Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania  
Luxembourg Netherlands Norway Poland 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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