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Ketexx 100 mg/ml solution for injection

Authorised

- Ketamine hydrochloride

Product identification

Medicine name:
Ketexx 100 mg/ml solution for injection

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

Product details

Active substance and strength:
Ketamine hydrochloride
115.30 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
- **Rabbit (exclusively kept as pet)**
  - All relevant tissues. no withdrawal period

Not authorised for use in rabbits for human consumption.

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

Intravenous use:

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

Rabbit (exclusively kept as pet)

- All relevant tissues. no withdrawal period

Not authorised for use in rabbits for human consumption.

- **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

Intraperitoneal use:

- **Rabbit (exclusively kept as pet)**
  - All relevant tissues. no withdrawal period

Not authorised for use in rabbits for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN01AX03

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

Authorisation status:
Valid

Authorised in:
Ireland

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

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:
Alfasan Nederland B.V.

Marketing authorisation date:
20/05/2022

Manufacturing sites for batch release:
Alfasan Nederland B.V.

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10980/016/001

Date of authorisation status change:
20/05/2022

Reference member state:

France

Procedure number:
FR/V/0435/001

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)

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

Documents

Combined File of all Documents

eu-puar-frv0435001-mr-rpe698-en.pdf