KELAPROFEN 100 mg/ml

Authorised

- Ketoprofen

Product identification

Medicine name:
KELAPROFEN 100 mg/ml
Kelaprofen 100 mg/ml, oplossing voor injectie voor runderen, paarden en varkens

Active substance:
Ketoprofen

Target species:
Cattle
Pig
Horse

Route of administration:
Intramuscular use
Intravenous use

Product details

Active substance and strength:
Ketoprofen
100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - Meat and offal. no withdrawal period — Meat and offal: IV: 1 day, IM: 2 days
- **Pig**
  - Meat and offal. 2 day
- **Cattle**
  - Milk. 0 hour

Intravenous use:

- **Cattle**
  - Meat and offal. no withdrawal period — Meat and offal: IV: 1 day, IM: 2 days
- **Horse**
  - Meat and offal. 1 day
- **Cattle**
  - Milk. 0 hour
- **Horse**
  - Milk. no withdrawal period

Milk: Its use is not authorized in animals whose milk is used for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QM01AE03

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

Authorisation status:
Valid

Authorised in:
Netherlands

Available in:
Netherlands

Package description:
box containing 12 vials of 250 ml
box containing 12 vials of 100 ml
box containing 12 vials of 50 ml
box containing 10 vials of 250 ml
box containing 10 vials of 100 ml
box containing 10 vials of 50 ml
box containing 6 vials of 250 ml
box containing 6 vials of 100 ml
box containing 6 vials of 50 ml
box containing 1 vial of 250 ml
box containing 1 vial of 100 ml
box containing 1 vial of 50 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:
KELA Kempisch Laboratorium Kela Laboratoria

Marketing authorisation date:

8/11/2011

Manufacturing sites for batch release:
KELA Kempisch Laboratorium Kela Laboratoria

Responsible authority:
Medicines Evaluation Board

Authorisation number:
REG NL 107687

Date of authorisation status change:
17/01/2022

Reference member state:
Spain

Procedure number:
ES/V/0160/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Ireland Italy Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia 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

English (PDF)

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Summary of Product Characteristics

Package Leaflet

Labelling

eu-PUAR-esv0160001-dcp-kelaprofen--100-mg-ml-en.pdf