Labiprofen 150 mg/ml solution for injection

Authorised

- Ketoprofen

Product identification

Medicine name:
Labiprofen 150 mg/ml solution for injection
LABIPROFEN 150 mg/ml ενέσιμο διάλυμα για βοοειδή, χοίρους και άλογα

Active substance:
Ketoprofen

Target species:
Cattle
Pig
Horse

Route of administration:
Intramuscular use
Intravenous use

Product details

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

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - Meat and offal. 2 day
  - Milk. 0 hour
- **Pig**
  - Meat and offal. 3 day
- **Cattle**
  - Meat and offal. 2 day
  - Milk. 0 hour
- **Horse**
  - Milk. no withdrawal period

Milk: Not authorised for use in mares producing milk for human consumption.

Intravenous use:

- **Cattle**
  - Meat and offal. 2 day
  - Milk. 0 hour
- **Horse**
  - Meat and offal. 1 day
- **Cattle**

- Meat and offal. 2 day
- Milk. 0 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QM01AE03

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

Authorisation status:
Valid

Authorised in:
Greece

Available in:
Greece

Package description:
box containing 10 vials of 250 ml
box containing 10 vials of 100 ml
box containing 12 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:
Labiana Life Sciences S.A.

Marketing authorisation date:

21/09/2021

Manufacturing sites for batch release:
LABIANA LIFE SCIENCES, S.A.

Responsible authority:
National Organization For Medicines

Authorisation number:
87507/22-09-2021 / K-0248301

Date of authorisation status change:
5/04/2022

Reference member state:
Spain

Procedure number:
ES/V/0388/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Sweden United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

English (PDF)

Published on: 12/04/2023

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Package Leaflet

Labelling

Combined File of all Documents