Labiprofen 150 mg/ml solution for injection

Authorised

- Ketoprofen

Product identification

Medicine name:
Labiprofen 150 mg/ml solution for injection
Labiprofen 150 mg/ml raztopina za injiciranje za govedo, prašiče in konje

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:
Slovenia

Available in:
Slovenia

Package description:
Available only in Slovenian
Available only in Slovenian
Available only in Slovenian
Available only in Slovenian
Available only in Slovenian
Available only in Slovenian

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:

31/03/2021

Manufacturing sites for batch release:
Labiana Life Sciences S.A.

Responsible authority:
Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

Authorisation number:
DC/V/0731/001

Date of authorisation status change:
31/03/2021

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

English (PDF)
Published on: 24/03/2023
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Labelling

English (PDF)
Published on: 24/03/2023
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Combined File of all Documents