

Labiprofen 150 mg/ml solution for injection

Authorised

- Ketoprofen

Product identification

Medicine name:

Labiprofen 150 mg/ml solution for injection

Active substance:

Ketoprofen

Target species:

Pig
Cattle
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:**

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Pig

- Meat and offal. 3 day

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Cattle

- Meat and offal. 2 day

- Milk. 0 hour

Intravenous use:

-

Horse

- Meat and offal. 1 day

- Milk. no withdrawal period

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

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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:

Austria

Available in:

Austria

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:

26/06/2023

Manufacturing sites for batch release:

Labiana Life Sciences S.A.

Responsible authority:

Austrian Agency For Health And Food Safety

Authorisation number:

841720

Date of authorisation status change:

26/06/2023

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

Combined File of all Documents

Package Leaflet

English (PDF)

Published on: 29/01/2024

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Labelling

English (PDF)

Published on: 29/01/2024

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Summary of Product Characteristics

English (PDF)

Published on: 29/01/2024

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