

Tolfine 80 mg/ml solution for injection for cattle

Authorised

- Tolfenamic acid

Product identification

Medicine name:

Tolfine 80 mg/ml solution for injection for cattle

Active substance:

Tolfenamic acid

Target species:

Cattle

Route of administration:

Intramuscular use
Intravenous use

Product details

Active substance and strength:

Tolfenamic acid
80.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:**Intramuscular use:**

-

Cattle

- Meat and offal. 20 day
- Milk. 0 hour

Intravenous use:

-

Cattle

- Meat and offal. 4 day
- Milk. 12 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QM01AG02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Denmark

Package description:

Amber type I glass vial closed with chlorobutyl rubber stoppers and oversealed with an aluminium seal with a polypropylene flip-off cap. Each vial is packaged in a cardboard box. Package sizes: Cardboard box with 1 vial of 250 ml

Amber type I glass vial closed with chlorobutyl rubber stopper and oversealed with an aluminium seal with a polypropylene flip-off cap. Each vial is packaged in a cardboard box. Package sizes: Cardboard box with 1 vial of 100 ml

Amber type I glass vial closed with chlorobutyl rubber stopper and oversealed with an aluminium seal with a polypropylene flip-off cap. Each vial is packaged in a cardboard box. Package sizes: Cardboard box with 1 vial of 50 ml

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Vetoquinol Scandinavia AB

Marketing authorisation date:

19/09/2022

Manufacturing sites for batch release:

Vetoquinol S.A.

Responsible authority:

Danish Medicines Agency

Authorisation number:

65946

Date of authorisation status change:

19/09/2022

Reference member state:

Ireland

Procedure number:

IE/V/0661/001

Concerned member states:

Austria Belgium Cyprus Czechia Denmark Estonia Finland France Germany
Greece Italy Latvia Lithuania Luxembourg Netherlands Poland Portugal
Slovakia Slovenia Spain

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

Documents

Summary of Product Characteristics

English (PDF)

Published on: 6/07/2025

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Combined File of all Documents