TOLFENIL 40 mg/ml solution for injection

Authorised

- Tolfenamic acid

Product identification

Medicine name:
TOLFENIL 40 mg/ml solution for injection
TOLFENIL 40 mg/ml, soluție injectabilă

Active substance:
Tolfenamic acid

Target species:
Cattle
Pig
Dog
Cat

Route of administration:
Intramuscular use
Intravenous use
Subcutaneous use

Product details

Active substance and strength:

Tolfenamic acid
40.00 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: 12 days intramuscular use / 4 days intravenous use

- **Pig**
  - Meat and offal. 16 day

- **Cattle**
  - Milk. no withdrawal period

Milk: Zero days intramuscular use/ 24 hours intravenous use

Intravenous use:

- **Cattle**
  - Meat and offal. no withdrawal period

Meat and offal: 12 days intramuscular use / 4 days intravenous use

- **Cattle**
  - Milk. no withdrawal period

Milk: Zero days intramuscular use/ 24 hours intravenous use

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QM01AG02

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

Authorisation status:
Valid

Authorised in:
Romania

Available in:
Romania

Package description:
Cardboard box with 15 vials of 250 ml
Cardboard box with 10 vials of 100 ml
Cardboard box with 5 vials of 20 ml
Cardboard box with 1 vial of 250 ml
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 20 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:
Mevet S.A.

Marketing authorisation date:
29/09/2021

Manufacturing sites for batch release:
Mevet S.A.

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
210147

Date of authorisation status change:
20/02/2025

Reference member state:
Spain

Procedure number:
ES/V/0383/001

Concerned member states:
Poland Portugal Romania

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

Documents

Summary of Product Characteristics

Combined File of all Documents

English (PDF)
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