HEMOSILATE 125 mg/ml solution for injection

Authorised

- Etamsylate

Product identification

Medicine name:
HEMOSILATE 125 mg/ml solution for injection

Active substance:
Etamsylate

Target species:
Cattle
Sheep
Goat
Pig
Horse
Dog
Cat

Route of administration:
Intravenous use
Intramuscular use

Product details

Active substance and strength:
Etamsylate
125.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intravenous use:

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

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

  - Milk. 0 day

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

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

  - Milk. 0 day

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

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

  - Milk. 0 day

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

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

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

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

  - Milk. 0 day

Intramuscular use:

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

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

  - Milk. 0 day

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

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

  - Milk. 0 day

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

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

  - Milk. 0 day

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

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

- **Horse**

- Meat and offal. no withdrawal period

Meat and offal: Adm. IV Zero days. Adm. IM 1 day

- Milk. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QB02BX01

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

Authorisation status:
Valid

Authorised in:
Greece

Available in:
Greece

Package description:
cardboard box containing 10 vials of 20 ml
cardboard box containing 5 vials of 20 ml
cardboard box containing 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:
Ecuphar Veterinaria S.L.U.

Marketing authorisation date:
19/10/2016

Manufacturing sites for batch release:
Zoetis Manufacturing & Research Spain S.L.

Responsible authority:
National Organization For Medicines

Authorisation number:
54852/13-05-2025/K-0225801

Date of authorisation status change:
12/05/2025

Reference member state:
Spain

Procedure number:
ES/V/0281/001

Concerned member states:
Austria Belgium Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Ireland Italy Malta Netherlands 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: 22/12/2023
Download

Package Leaflet

English (PDF)
Published on: 22/12/2023
Download

eu-PUAR-esv0281001-dcp-hemosilate-125-mg-ml-solution-for-injection-en.pdf