

Entemulin, 450mg/g, Granules for use in drinking water

Authorised

- Tiamulin hydrogen fumarate

Product identification

Medicine name:

Entemulin, 450mg/g, Granules for use in drinking water

Active substance:

Tiamulin hydrogen fumarate

Target species:

Pig

Chicken

Turkey

Route of administration:

In drinking water use

Product details

Active substance and strength:

Tiamulin hydrogen fumarate

450.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:

Granules for use in drinking water

Withdrawal period by route of administration:

In drinking water use:

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Pig

- Meat and offal. 4 day

(20 mg tiamulin hydrogen fumarate (equivalent to 44.4 mg of veterinary medicinal product)/kg body weight).

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Chicken

- Meat and offal. 2 day

- Egg. 0 day

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Turkey

- Meat and offal. 6 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01XQ01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Romania

Available in:

Romania

Package description:

Plastic Bag 1 x 1.0 kilogram(s) PET/AL/LDPE

Plastic Bag 1 x 5.0 kilogram(s) PET/AL/LDPE

Plastic Bag 1 x 10.0 kilogram(s) PET/AL/LDPE

Plastic Bag 1 x 1.0 kilogram(s) papír/papír/HDPE
Plastic Bag 1 x 5.0 kilogram(s) papír/papír/HDPE
Plastic Bag 1 x 10.0 kilogram(s) papír/papír/HDPE

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:

KRKA tovarna zdravil d.d. Novo mesto

Marketing authorisation date:

19/01/2017

Manufacturing sites for batch release:

KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:

Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:

170026

Date of authorisation status change:

17/08/2025

Reference member state:

Czechia

Procedure number:

CZ/V/0109/001

Concerned member states:

Hungary Lithuania Poland Romania Slovakia Slovenia

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

Documents

Combined File of all Documents

This document does not exist in this language (English). You can find it in another language below.

Summary of Product Characteristics

Package Leaflet