Tyawalt 450 mg/g granules for use in drinking water for pigs

Authorised

- Tiamulin hydrogen fumarate

Product identification

Medicine name:
Tyawalt 450 mg/g granules for use in drinking water for pigs
Tyawalt 450 mg/g Granulaat voor gebruik in drinkwater
Tyawalt 450 mg/g Granulés pour administration dans l'eau de boisson
Tyawalt 450 mg/g Granulat zum Eingeben über das Trinkwasser

Active substance:
Tiamulin hydrogen fumarate

Target species:
Pig

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:

- **Pig**
  - Meat and offal. 2 day

(8.8 mg tiamulin hydrogen fumarate (equivalent to 19.6 mg of product)/kg body weight).

- Meat and offal. 4 day

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

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01XQ01

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

Authorisation status:
Valid

Authorised in:
Belgium

Package description:
(ID2) 5 kilogram(s): unspecified outer container with 1 Bag (Low Density PolyEthylene; Aluminium; PolyEthylene TerePhthalate) with 5 kilogram(s)
(ID1) 1 kilogram(s): unspecified outer container with 1 Bag (Low Density PolyEthylene; Aluminium; PolyEthylene TerePhthalate) with 1 kilogram(s)

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:
1/03/2018

Manufacturing sites for batch release:
KRKA tovarna zdravil d.d. Novo mesto
TAD Pharma GmbH

Responsible authority:
Federal Agency For Medicines And Health Products

Authorisation number:
BE-V526124

Date of authorisation status change:
1/03/2018

Reference member state:
Germany

Procedure number:
DE/V/0264/001

Concerned member states:
Belgium Denmark France Netherlands Portugal Spain
United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

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

Package Leaflet

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