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 voor varkens, kippen en kalkoenen

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:
Netherlands

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:
31/01/2018

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

Responsible authority:
Medicines Evaluation Board

Authorisation number:
REG NL 117121

Date of authorisation status change:
8/02/2022

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