HYDROTRIM 500 MG/G + 100 MG/G POWDER FOR USE IN DRINKING WATER/MILK FOR CATTLE, SHEEP, PIGS AND CHICKENS

Authorised

- Sulfadiazine sodium
- Trimethoprim

Product identification

Medicine name:
HYDROTRIM 500 MG/G + 100 MG/G POWDER FOR USE IN DRINKING WATER/MILK FOR CATTLE, SHEEP, PIGS AND CHICKENS
Hydrotrim 500+100 mg/g pulver til anvendelse i drikkevand/mælk

Active substance:
Sulfadiazine sodium
Trimethoprim

Target species:
Cattle (pre-ruminant)
Sheep (lamb)
Chicken
Pig

Route of administration:
In drinking water/milk use
In drinking water use

Product details

Active substance and strength:
Sulfadiazine sodium
543.90 milligram(s) / 1.00 gram(s)

Trimethoprim
100.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:
Powder for use in drinking water/milk

Withdrawal period by route of administration:
In drinking water/milk use:

- **Cattle (pre-ruminant)**
  - Meat and offal. 12 day

- **Sheep (lamb)**
  - Meat and offal. 12 day

In drinking water use:

- **Chicken**
  - Eggs. no withdrawal period

Not for use in birds producing or intended to produce eggs for human consumption

  - Meat and offal. 12 day

- **Pig**
  - Meat and offal. 12 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01EW10

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

Authorisation status:
Valid

Authorised in:
Denmark

Available in:
Denmark

Package description:
1 kg resealable block -bottom zipped sachet made of polyethylene/aluminium/polyethylene terephthalate laminate.
100 g pillow sachet made of polyethylene/aluminium/polyethylene terephthalate laminate.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:
HuVepharma

Marketing authorisation date:
23/08/2023

Manufacturing sites for batch release:
Biovet AD

Responsible authority:

Danish Medicines Agency

Authorisation number:
67816

Date of authorisation status change:
23/08/2023

Reference member state:
France

Procedure number:
FR/V/0457/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Malta Netherlands Poland Portugal Romania Slovakia Slovenia Spain United Kingdom (Northern Ireland)

Generic of:
600000039940

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

Documents

Summary of Product Characteristics

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