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FLUDOSOL 200 MG/ML SUSPENSION FOR USE IN DRINKING WATER FOR PIGS AND CHICKENS

Authorised

- Flubendazole

Product identification

Medicine name:
FLUDOSOL 200 MG/ML SUSPENSION FOR USE IN DRINKING WATER FOR PIGS AND CHICKENS

Active substance:
Flubendazole

Target species:
Chicken
Pig

Route of administration:
In drinking water use

Product details

Active substance and strength:

Flubendazole
200.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Suspension for use in drinking water

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

- **Chicken**
  - Meat and offal. 2 day
  - Eggs. 0 day
- **Pig**
  - Meat and offal. 4 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP52AC12

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

Authorisation status:
Valid

Authorised in:
Denmark

Package description:
Round bottle of 250 mL
Jerrycan of 5 L
Round bottle of 1L with HDPE cap
Round bottle of 1 L with LDPE cap

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Dopharma Research B.V.

Marketing authorisation date:
31/05/2023

Manufacturing sites for batch release:
Dopharma B.V.
Dopharma France

Responsible authority:
Danish Medicines Agency

Authorisation number:
66923

Date of authorisation status change:
31/05/2023

Reference member state:
France

Procedure number:
FR/V/0449/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Spain Sweden

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

Documents

Summary of Product Characteristics

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Combined File of all Documents

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