# Gallifen 200 mg/ml suspension for use in drinking water for chickens and pheasants

Authorised

• Fenbendazole

# Product identification

#### **Medicine name:**

Gallifen 200 mg/ml suspension for use in drinking water for chickens and pheasants Gallifen 200 mg/ml εναιώρημα για χορήγηση με πόσιμο νερό για ορνίθια και φασιανούς

#### **Active substance:**

Fenbendazole

## **Target species:**

Chicken

Pheasant

#### Route of administration:

In drinking water use

# **Product details**

# **Active substance and strength:**

Fenbendazole 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
  - Eggs. 0 day
  - Meat and offal. 8 day  $_{\ast}$  when used at 3 mg fenbendazole / kg bw / day
  - Meat and offal. 6 day
- Pheasant
  - Eggs. 0 day
  - Meat and offal. 6 day

Do not release pheasants for hunting for at least 6 days after the end of medication.

## Anatomical therapeutic chemical veterinary (ATCvet) codes:

QP52AC13

# Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

#### **Authorisation status:**

Valid

#### **Authorised in:**

Cyprus

## Package description:

White rectangular HDPE bottle of 1 litre with vertically see-through bar with an LDPE insert closed with white PP tamper- evident screw cap with a LDPE sealing disk.

White HDPE canisters with white HDPE ribbed tamper-evident screw cap of 5 litres.

White HDPE canisters with white HDPE ribbed tamper-evident screw cap of 2.5 litres.

White cylindrical High Density Polyethylene (HDPE) bottle with white polypropylene (PP) screw tamper-evident closure of 1 litre.

White cylindrical High Density Polyethylene (HDPE) bottle with white polypropylene (PP) screw tamper-evident closure of 125 ml.

# 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:

HuVepharma

## Marketing authorisation date:

25/02/2019

## Manufacturing sites for batch release:

Biovet J.S.C.

## **Responsible authority:**

Veterinary Services, Ministry Of Agriculture, Natural Resources And Environment

## **Authorisation number:**

CY00663V

# Date of authorisation status change:

25/02/2019

#### Reference member state:

Ireland

#### **Procedure number:**

IE/V/0579/001

#### **Concerned member states:**

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia France Germany Greece Hungary Italy Latvia Lithuania Luxembourg Netherlands Poland Portugal Romania Slovakia Slovenia 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

Combined File of all Documents

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