# Enterisol lleitis lyophilisate and diluent for oral suspension for pigs

Authorised

• Lawsonia intracellularis, strain MS B3903, Live

# Product identification

#### Medicine name:

Enterisol lleitis lyophilisate and diluent for oral suspension for pigs Enterisol lleitis liofilizat i rozpuszczalnik do sporządzania zawiesiny doustnej dla świń

#### **Active substance:**

Lawsonia intracellularis, strain MS B3903, Live

## **Target species:**

Pig

## Route of administration:

Oral use

# **Product details**

# **Active substance and strength:**

Lawsonia intracellularis, strain MS B3903, Live 1258930.00 tissue culture infective dose 50 / 1.00 Dose

## **Pharmaceutical form:**

Lyophilisate and solvent for oral suspension

# Withdrawal period by route of administration:

## Oral use:

- Pig
  - Meat and offal. no withdrawal period Withdrawal period is 0 days

# Anatomical therapeutic chemical veterinary (ATCvet) codes:

**Q109AE04** 

## **Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

## **Authorisation status:**

Valid

### **Authorised in:**

Poland

## Package description:

(ID8): 1 Box with 12 Box with (1 Bottle (Glass) with 100 Dose and 1 Bottle (High Density PolyEthylene) with 200 millilitre(s)) (1200.0 Dose, 2400.0 millilitre(s))

(ID6): 1 Box with (1 Bottle (Glass) with 100 Dose and 1 Bottle (High Density

PolyEthylene) with 200 millilitre(s)) (100.0 Dose, 200.0 millilitre(s))

(ID4): 1 Box with (1 Bottle (Glass) with 50 Dose and 1 Bottle (High Density PolyEthylene) with 100 millilitre(s)) (50.0 Dose, 100.0 millilitre(s))

(ID2): 1 Box with (1 Bottle (Glass) with 10 Dose and 1 Bottle (High Density

PolyEthylene) with 20 millilitre(s)) (10.0 Dose, 20.0 millilitre(s))

# Additional information

# **Entitlement type:**

Marketing Authorisation

# Legal basis of product authorisation:

Immunological veterinary medicinal product application (Article 13d of Directive No 2001/82/EC)

# Marketing authorisation holder:

## Boehringer Ingelheim Vetmedica GmbH

## Marketing authorisation date:

19/08/2005

# Manufacturing sites for batch release:

Boehringer Ingelheim Vetmedica GmbH

## **Responsible authority:**

Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

## **Authorisation number:**

1624

## Date of authorisation status change:

4/03/2010

## Reference member state:

Germany

## **Procedure number:**

DE/V/0236/001

## **Concerned member states:**

Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia Finland France Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to <a href="https://www.adrreports.eu/vet">www.adrreports.eu/vet</a>

# **Documents**

Summary of Product Characteristics

English (PDF)

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Labelling

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Package Leaflet

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