PORCILIS LAWSONIA LYOPHILISATE AND SOLVENT FOR EMULSION FOR INJECTION FOR PIGS

Authorised

- Lawsonia intracellularis, strain SPAH-08, Inactivated

Product identification

Medicine name:
PORCILIS LAWSONIA LYOPHILISATE AND SOLVENT FOR EMULSION FOR INJECTION FOR PIGS

Active substance:
Lawsonia intracellularis, strain SPAH-08, Inactivated

Target species:
Pig (for fattening)
Pig (for reproduction)

Route of administration:
Intramuscular use

Product details

Active substance and strength:

Lawsonia intracellularis, strain SPAH-08, Inactivated
5323.00 unit(s) / 1.00 Dose

Pharmaceutical form:
Lyophilisate and solvent for emulsion for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Pig (for fattening)**
  - All relevant tissues. 0 day

- **Pig (for reproduction)**
  - All relevant tissues. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI09AB18

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

Authorisation status:
Valid

Authorised in:
Czechia

Available in:
Czechia

Package description:
Cardboard box with 1 x 50 doses of vaccine and cardboard box with 1 x 100 ml solvent
Cardboard box with 10 x 100 doses of vaccine and cardboard box with 10 x 200 ml solvent
Cardboard box with 1 x 100 doses of vaccine and cardboard box with 1 x 200 ml solvent

Cardboard box with 10 x 50 doses of vaccine and cardboard box with 10 x 100 ml solvent

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - New active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Intervet International B.V.

Marketing authorisation date:
29/08/2019

Manufacturing sites for batch release:
Intervet International B.V.

Responsible authority:
Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number:
97/068/19-C

Date of authorisation status change:
29/08/2019

Reference member state:
France

Procedure number:
FR/V/0357/001

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

Slovenia Spain Sweden United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Labelling

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

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