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PORCILIS LAWSONIA ID LYOPHILISATE AND SOLVENT FOR EMULSION FOR INJECTION FOR PIGS

Authorised

- Lawsonia intracellularis, strain SPAH-08, Inactivated

Product identification

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

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

Target species:
Pig

Route of administration:
Intradermal use

Product details

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

5323.00 unit(s) / 1.00 unit(s)

Pharmaceutical form:
Lyophilisate and solvent for emulsion for injection

Withdrawal period by route of administration:
Intradermal use:

- **Pig**
  - 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:
Denmark

Available in:
Denmark

Package description:
Cardboard box with 1 x 200 doses of vaccine and cardboard box with 1 x 40 ml solvent
Cardboard box with 10 x 200 doses of vaccine and cardboard box with 10 x 40 ml solvent
Cardboard box with 1 x 50 doses of vaccine and cardboard box with 1 x 10 ml solvent
Cardboard box with 10 x 50 doses of vaccine and cardboard box with 10 x 10 ml solvent
Cardboard box with 1 x 100 doses of vaccine and cardboard box with 1 x 20 ml solvent
Cardboard box with 10 x 100 doses of vaccine and cardboard box with 10 x 20 ml solvent

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Intervet International B.V.

Marketing authorisation date:
2/03/2021

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

Responsible authority:
Danish Medicines Agency

Authorisation number:
63588

Date of authorisation status change:
2/03/2021

Reference member state:
France

Procedure number:
FR/V/0424/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland Germany 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 www.adrreports.eu/vet

Documents

Summary of Product Characteristics

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Combined File of all Documents

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