

# 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

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**Active substance:**

Lawsonia intracellularis, strain SPAH-08, Inactivated

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**Target species:**

Pig (for fattening)  
Pig (for reproduction)

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**Route of administration:**

Intramuscular use

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## Product details

**Active substance and strength:**

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

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**Pharmaceutical form:**

Lyophilisate and solvent for emulsion for injection

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**Withdrawal period by route of administration:**

**Intramuscular use:**

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**Pig (for fattening)**

- All relevant tissues. 0 day

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**Pig (for reproduction)**

- All relevant tissues. 0 day

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QI09AB18

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Romania

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**Available in:**

Romania

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**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

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Full application - New active substance (Article 12(3) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Intervet Nederland B.V.

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**Marketing authorisation date:**

28/08/2019

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**Manufacturing sites for batch release:**

Intervet International B.V.

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**Responsible authority:**

Institute For Control Of Biological Products And Veterinary Medicines

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**Authorisation number:**

240121

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**Date of authorisation status change:**

27/08/2024

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**Reference member state:**

France

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**Procedure number:**

FR/V/0357/001

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**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)

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To consult adverse reactions on veterinary medicinal products please go to [www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Combined File of all Documents

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eu-puar-frv0357001-mr-rpe784-en.pdf