

# Ingelvac PRRSFLEX EU

## lyophilisate and solvent for suspension for injection for pigs

Authorised

- Porcine reproductive and respiratory syndrome virus, type 1, strain PRRS 94881, Live

## Product identification

**Medicine name:**

Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs

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**Active substance:**

Porcine reproductive and respiratory syndrome virus, type 1, strain PRRS 94881, Live

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**Target species:**

Pig

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**Route of administration:**

Intramuscular use

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## Product details

**Active substance and strength:**

Porcine reproductive and respiratory syndrome virus, type 1, strain PRRS 94881, Live  
3981070.00 50% tissue culture infectious dose / 1.00 millilitre(s)

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**Pharmaceutical form:**

Lyophilisate and solvent for suspension for injection

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**Withdrawal period by route of administration:****Intramuscular use:**

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**Pig**

- Meat and offal. 0 day

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

QI09AD03

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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:**

Netherlands

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**Available in:**

Netherlands

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**Package description:**

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 1 lyophilisate vial of 10 ml (10 doses) and 1 solvent vial of 10 ml packed in one cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 1 lyophilisate vial of 50 ml (50 doses) and 1 solvent vial of 50 ml packed in one cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 1 lyophilisate vial of 100 ml (100 doses) and 1 solvent vial of 100 ml packed in one cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 1 lyophilisate vial of 250 ml (250 doses) and 1 solvent vial of 250 ml packed in one cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. 12 lyophilisate vials of 10 ml (10 doses) packed in a separate cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. 12 lyophilisate vials of 50 ml (50 doses) packed in a separate cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. 12 lyophilisate vials of 100 ml (100 doses) packed in a separate cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. 12 lyophilisate vials of 250 ml (250 doses) packed in a separate cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. 25 lyophilisate vials of 10 ml (10 doses) packed in a separate cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. 25 lyophilisate vials of 50 ml (50 doses) packed in a separate cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. 25 lyophilisate vials of 100 ml (100 doses) packed in a separate cardboard box.

Lyophilisate: Type I amber glass vials with bromobutyl rubber stopper and aluminium seal. 25 lyophilisate vials of 250 ml (250 doses) packed in a separate cardboard box.

Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 12 solvent vials of 10 ml packed in a separate cardboard box.

Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 12 solvent vials of 50 ml packed in a separate cardboard box.

Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 12 solvent vials of 100 ml packed in a separate cardboard box.

Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 12 solvent vials of 250 ml packed in a separate cardboard box.

Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 25 solvent vials of 10 ml packed in a separate cardboard box.

Solvent: High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 25 solvent vials of 50 ml packed in a separate cardboard box.

box.

Solvent:High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 25 solvent vials of 100 ml packed in a separate cardboard box.

Solvent:High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal. 25 solvent vials of 250 ml packed in a separate cardboard box.

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Full application (Article 12(3) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Boehringer Ingelheim Vetmedica GmbH

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**Marketing authorisation date:**

10/04/2015

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**Manufacturing sites for batch release:**

Boehringer Ingelheim Vetmedica GmbH

Norbrook Laboratories (Ireland) Limited

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**Responsible authority:**

Medicines Evaluation Board

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**Authorisation number:**

REG NL 115061

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**Date of authorisation status change:**

29/03/2022

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**Reference member state:**

Ireland

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**Procedure number:**

IE/V/0443/001

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**Concerned member states:**

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

English (PDF)

Published on: 6/07/2025

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Summary of Product Characteristics