

# UNISTRAIN PRRS lyophilisate and solvent for suspension for injection for pigs

Authorised

- Porcine reproductive and respiratory syndrome virus, type 1, strain VP-046 BIS, Live

## Product identification

**Medicine name:**

UNISTRAIN PRRS lyophilisate and solvent for suspension for injection for pigs

---

**Active substance:**

Porcine reproductive and respiratory syndrome virus, type 1, strain VP-046 BIS, Live

---

**Target species:**

Pig

---

**Route of administration:**

Intradermal use  
Intramuscular use

---

## Product details

**Active substance and strength:**

Porcine reproductive and respiratory syndrome virus, type 1, strain VP-046 BIS, Live  
316228.00 50% cell culture infectious dose / 1.00 Dose

---

**Pharmaceutical form:**

Lyophilisate and solvent for suspension for injection

---

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

- 

**Pig**

- Meat and offal. 0 day

**Intramuscular use:**

- 

**Pig**

- Meat and offal. 0 day

---

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

QI09AD03

---

**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

---

**Authorisation status:**

Valid

---

**Authorised in:**

Luxembourg

---

**Package description:**

Intramuscular use: Cardboard box containing 1 vial with 10 doses of freeze-dried powder and 1 vial with 20 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: Colourless Type I glass vial (20ml)

Intramuscular use: Cardboard box containing 1 vial with 25 doses of freeze-dried powder and 1 vial with 50 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: Type II glass vial (50 ml)

Intramuscular use: Cardboard box containing 1 vial with 50 doses of freeze-dried powder and 1 vial with 100 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent:

Type II glass vial (100 ml)

Intramuscular use: Cardboard box containing 1 vial with 125 doses of freeze-dried powder and 1 vial with 250 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent:

Type II glass vial (250 ml)

Intramuscular use: Cardboard box containing 10 vials with 10 doses of freeze-dried powder. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 10 vials with 25 doses of freeze-dried powder. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 10 vials with 50 doses of freeze-dried powder. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 10 vials with 100 doses of freeze-dried powder. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 10 vials with 125 doses of freeze-dried powder. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 10 vials with 20 ml of solvent. Solvent: Colourless Type I glass vial (20 ml)

Intramuscular use: Cardboard box containing 10 vials with 50 ml of solvent. Solvent: Colourless Type II glass vial (50 ml)

Intramuscular use: Cardboard box containing 10 vials with 100 ml of solvent. Solvent: Colourless, Type II glass vial (100 ml)

Intramuscular use: Cardboard box containing 10 vials with 250 ml of solvent. Solvent: Colourless, Type II glass vial (250 ml)

Intradermal use: Cardboard box containing 1 vial with 50 doses of freeze-dried powder and 1 vial with 10 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: Colourless Type I glass vial (10 ml)

Intradermal use: Cardboard box containing 1 vial with 100 doses of freeze-dried powder and 1 vial with 20 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: Colourless Type I glass vial (20 ml)

Intradermal use:Cardboard box containing 1 vial with 250 doses of freeze-dried powder and 1 vial with 50 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: Colourless , Type II glass vial (50 ml)

Intradermal use:Cardboard box containing 10 vials with 50 doses of freeze-dried powder. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use:Cardboard box containing 10 vials with 100 doses of freeze-dried powder. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use:Cardboard box containing 10 vials with 125 doses of freeze-dried powder. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use:Cardboard box containing 10 vials with 250 doses of freeze-dried powder. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use:Cardboard box containing 10 vials with 50 ml of solvent. Solvent: Colourless Type II glass vial (50 ml)

Intradermal use:Cardboard box containing 10 vials with 20 ml of solvent. Solvent: Colourless Type I glass vial (20 ml)

Intradermal use:Cardboard box containing 10 vials with 10 ml of solvent. Solvent: Colourless Type I glass vial (10 ml)

Intradermal use: Cardboard box containing 10 vials with 25 ml of solvent. Solvent: PET vial (50 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use:Cardboard box containing 10 vials with 200 ml of solvent. Solvent: PET vial (250 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use:Cardboard box containing 10 vials with 200 ml of solvent. Solvent: Colourless Type II glass vial (250 ml)

Intradermal use: Cardboard box containing 1 vial with 125 doses of freeze-dried powder and 1 vial with 25 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: PET vial (50 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use:Cardboard box containing 1 vial with 125 doses of freeze-dried powder and 1 vial with 25 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: Colourless Type II glass vial (50 ml)

Intramuscular use: Cardboard box containing 1 vial with 100 doses of freeze-dried powder and 1 vial with 200 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: Colourless Type II glass vial (250 ml)

Intradermal use: Cardboard box containing 10 vials with 50 ml of solvent. PET vials (50 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use: Cardboard box containing 10 vials with 20 ml of solvent. PET vials (20 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use: Cardboard box containing 10 vials with 10 ml of solvent. PET vials (10 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use: Cardboard box containing 1 vial with 250 doses of freeze-dried powder and 1 vial with 50 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: PET vial (50 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use: Cardboard box containing 1 vial with 100 doses of freeze-dried powder and 1 vial with 20 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: PET vial (20 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use: Cardboard box containing 1 vial with 50 doses of freeze-dried powder and 1 vial with 10 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: PET vial (10 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 10 vials with 250 ml of solvent. PET vials (250 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 10 vials with 100 ml of solvent. PET vials (100 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 10 vials with 50 ml of solvent. PET vials (50 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 10 vials with 20 ml of solvent. PET vials (20 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 1 vial with 125 doses of freeze-dried powder and 1 vial with 250 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: PET vial (250 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 1 vial with 50 doses of freeze-dried powder and 1 vial with 100 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: PET vial

(100 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 1 vial with 25 doses of freeze-dried powder and 1 vial with 50 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: PET vial (50 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intramuscular use: Cardboard box containing 1 vial with 10 doses of freeze-dried powder and 1 vial with 20 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: PET vial (20 ml) closed with a bromobutyl rubber closure and an aluminium cap.

Intradermal use: Cardboard box containing 10 vials with 25 ml of solvent. Solvent: Type II glass vial (50 ml)

Intramuscular use: Cardboard box containing 1 vial with 100 doses of freeze-dried powder and 1 vial with 200 ml of solvent. Freeze-dried powder: Colourless Type I glass vial closed with a bromobutyl rubber closure and an aluminium cap. Solvent: PET vial (250ml) closed with a bromobutyl rubber closure and an aluminium cap.

---

## Additional information

**Entitlement type:**

Marketing Authorisation

---

**Legal basis of product authorisation:**

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

---

**Marketing authorisation holder:**

Laboratorios Hipra S.A.

---

**Marketing authorisation date:**

13/01/2016

---

**Manufacturing sites for batch release:**

Laboratorios Hipra S.A.

---

**Responsible authority:**

Ministry Of Health And Social Security

---

**Authorisation number:**

V 510/13/05/1306

---

**Date of authorisation status change:**

13/01/2016

---

**Reference member state:**

Ireland

---

**Procedure number:**

IE/V/0287/001

---

**Concerned member states:**

Austria Belgium Bulgaria Croatia Czechia Denmark Estonia France  
Germany Greece Hungary Italy Latvia Lithuania Luxembourg Malta  
Netherlands Poland Portugal Romania Slovakia Slovenia Spain  
United Kingdom (Northern Ireland)

---

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

## Documents

Summary of Product Characteristics

Combined File of all Documents