

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

Not  
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

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**Active substance:**

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

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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:**

Surrendered

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**Authorised in:**

Malta

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**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.

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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:**

Laboratorios Hipra S.A.

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### **Marketing authorisation date:**

30/01/2013

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### **Manufacturing sites for batch release:**

Laboratorios Hipra, S.A.

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### **Responsible authority:**

Veterinary And Phytosanitary Regulation Department

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### **Authorisation number:**

VMA24

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### **Date of authorisation status change:**

30/01/2013

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### **Reference member state:**

Ireland

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**Procedure number:**

IE/V/0287/001

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