File downloaded on 2026-04-28
Source URL: https://medicines.health.europa.eu/veterinary/en/600000089656

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:
Poland

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:
12/06/2013

Manufacturing sites for batch release:
Laboratorios Hipra S.A.

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
2293

Date of authorisation status change:
12/06/2013

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

Documents

Summary of Product Characteristics

English (PDF)
Published on: 24/08/2025
Updated on: 13/03/2026
Download

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Labelling

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents