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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:
Germany

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

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:
13/03/2013

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

Responsible authority:
Paul-Ehrlich-Institut

Authorisation number:
PEI.V.11596.01.1

Date of authorisation status change:
21/07/2017

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)

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Documents

Combined File of all Documents

English (PDF)
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Summary of Product Characteristics