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

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

Authorised

Product identification

Medicine name:
Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs
INGELVAC PRRSFLEX EU LYOPHILISAT ET INGELVAC PRRSFLEX EU SOLVANT POUR SUSPENSION INJECTABLE POUR PORCINS
Active substance:

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

Target species:

- Pig

Route of administration:

- Intramuscular use

Product details

Active substance and strength:

- Porcine reproductive and respiratory syndrome virus, type 1, strain PRRS 94881, Live
  3981070.00
  tissue culture infective dose 50
  /
  1.00
  millilitre(s)
- Water for injection
  1.00
  other
  /
  1.00
  millilitre(s)

Pharmaceutical form:

- Lyophilisate and solvent for suspension for injection

Withdrawal period by route of administration:

- 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:

- France

Package description:

- 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.
- 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 50 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. 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. 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 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 10 ml 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 separatecardboard 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 separatecardboard 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 separatecardboard 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 separatecardboard 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 separatecardboard 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 separatecardboard 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 separatecardboard 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 separatecardboard 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.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 50 ml (50 doses) and 1 solvent vial of 50ml 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 10 ml (10 doses) and 1 solvent vial of 10 ml packed in one cardboard box.

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:

- Boehringer Ingelheim Animal Health France

Marketing authorisation date:

- 3/03/2015

Manufacturing sites for batch release:

- Boehringer Ingelheim Vetmedica GmbH
- Norbrook Laboratories (Ireland) Limited

Responsible authority:

- French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:

- FR/V/8612502 0/2015

Date of authorisation status change:

- 16/03/2020

Reference member state:

- Ireland

Procedure number:

- IE/V/0443/001

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)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Product information

Summary of Product Characteristics

English (PDF)

Published on: 3/05/2024
Download
Other languages (1)
French (PDF)
Published on: 7/04/2022
Download
