

Ingelvac PRRSFLEX EU

lyophilisate and solvent for suspension for injection for pigs

Authorised

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

Product identification

Medicine name:

Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs
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Active substance:

Porcine reproductive and respiratory syndrome virus, type 1, strain PRRS 94881, Live

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 50% tissue culture infectious dose / 1.00 millilitre(s)

Pharmaceutical form:

Lyophilisate and solvent for suspension for injection

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

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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:

Ireland

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 Vetmedica GmbH

Marketing authorisation date:

2/04/2015

Manufacturing sites for batch release:

Boehringer Ingelheim Vetmedica GmbH
Norbrook Laboratories (Ireland) Limited

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10454/008/001

Date of authorisation status change:

2/04/2015

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 Norway 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

Combined File of all Documents