FIXR PRRS inac

Authorised

- Porcine reproductive and respiratory syndrome virus, type 1, strain Bio-60, Inactivated
- Porcine reproductive and respiratory syndrome virus, type 2, strain Bio-61, Inactivated

Product identification

Medicine name:
FIXR PRRS inac
FIXR PRRS inac, emulsie voor injectie voor varkens

Active substance:
Porcine reproductive and respiratory syndrome virus, type 1, strain Bio-60, Inactivated

Porcine reproductive and respiratory syndrome virus, type 2, strain Bio-61, Inactivated

Target species:
Pig (sow)

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Porcine reproductive and respiratory syndrome virus, type 1, strain Bio-60, Inactivated

1.00 relative potency / 2.00 millilitre(s)

Porcine reproductive and respiratory syndrome virus, type 2, strain Bio-61, Inactivated
1.00 relative potency / 2.00 millilitre(s)

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Pig (sow)**
  - All relevant tissues. no withdrawal period zero days

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI09AA05

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Netherlands

Package description:
1 × 10 ml (1 x 5 doses) - glass vials hydrolytic class I or plastic HDPE vials closed with chlorobutyl rubber stoppers, sealed with aluminum caps in a cardboard box.
10 x 10 ml (10 x 5 doses) - glass vials hydrolytic class I or plastic HDPE vials closed with chlorobutyl rubber stoppers, sealed with aluminum caps in a cardboard box with a grid or PVC box.
1 × 50 ml (1 x 25 doses) - glass vials hydrolytic class II or plastic HDPE vials closed with chlorobutyl rubber stoppers, sealed with aluminum caps in a cardboard box.
1 × 100 ml (1 x 50 doses) - glass vials hydrolytic class II or plastic HDPE vials closed with chlorobutyl rubber stoppers, sealed with aluminum caps in a cardboard box.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Kernfarm B.V.

Marketing authorisation date:
7/01/2021

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Medicines Evaluation Board

Authorisation number:
REG NL 125906

Date of authorisation status change:
24/01/2022

Reference member state:
Netherlands

Procedure number:
NL/V/0342/001

Concerned member states:
Belgium France Germany Portugal Spain

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

Documents

Combined File of all Documents

English (PDF)
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