SPC

Porcilis® PRRS

SUMMARY OF PRODUCT CHARACTERISTICS

June 2013 (UK/V/0145/001/IB/014_December 2013)

MSD Animal Health

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PRRS
Lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2 ml (intramuscular application) or 0.2 ml (intradermal application) of reconstituted vaccine:

Lyophilisate:
Active substance:
Live attenuated PRRS virus strain DV: $10^{4.0}$ - $10^{6.3}$ $TCID_{50}$ *

Solvent (Diluvac Forte):
Adjuvant:
dl-α-tocopheryl acetate: 75 mg/ml

For a full list of excipients, see section 6.1.

*tissue culture infective dose 50 %

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species
Pigs.

4.2 Indications for use, specifying the target species
For active immunisation of clinically healthy pigs in a PRRS virus contaminated environment, to reduce viraemia caused by infection with European strains of PRRS virus.

Specific claims
For finishing pigs, the effect of the virus on the respiratory system is most relevant. A significant improvement of rearing results (reduced morbidity due to PRRS infection, and a better daily growth and feed conversion) until the end of the fattening period was observed in vaccinated pigs during field trials, particularly in piglets vaccinated at 6 weeks of age.
For breeding pigs, the effect of the virus on the reproductive system is most relevant. A significant improvement of the reproductive performance in PRRS virus contaminated environments and a reduction of transplacental virus transmission after challenge was observed in vaccinated pigs.

The interest of vaccination with Porcilis PRRS lies in obtaining a homogeneous and high immune status against PRRS virus in a herd.
Immunity has been demonstrated via challenge at 28 days post vaccination. A duration of immunity of at least 24 weeks has been demonstrated.

4.3 Contraindications
Do not use in herds where the prevalence of European PRRS virus has not been established through reliable diagnostic methods.

4.4 Special warnings for each target species
Porcilis PRRS must only be used in PRRS virus contaminated herds, where prevalence of European PRRS virus has been established through reliable diagnostic virological methods. No data are available on the safety of the vaccine for the reproductive performance in boars. Do not use in herds where a PRRS eradication programme based on serology has been adopted.

4.5 Special precautions for use

Special precautions for use in animals
Care should be taken to avoid the introduction of the vaccine strain into an area where PRRS virus is not already present. The vaccine virus may spread to pigs in contact during 5 weeks after vaccination. The most common spreading route is via direct contact, but spreading via contaminated objects or via the air cannot be excluded. Care should be taken to avoid spread of vaccine virus from vaccinated animals to unvaccinated animals (e.g.: naïve pregnant sows) that should remain free from PRRS virus. Do not use in boars producing semen for seronegative herds, as PRRS virus may be excreted in semen for many weeks.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)
Systemic or local reactions may be observed after vaccination. After intramuscular vaccination a transient hyperthermia may occur. In rare cases the vaccination can evoke hypersensitivity reactions such as dyspnoea, hyperaemia, decubitus, tremor, excitation and vomiting. These signs normally disappear spontaneously and totally within a few minutes after vaccination, however, in very rare cases fatal anaphylactic reactions have occurred.
A small firm intradermal lump (1.5 cm in diameter maximally) observed after the intradermal application is indicative of the appropriate vaccination technique. This dermal lump is generally seen for less than 14 days but may occasionally persist for 29 days or longer.

4.7 Use during pregnancy, lactation or lay

PRRS virus-naïve gilts and sows should not be vaccinated during pregnancy, as this can have negative effects. Vaccination during pregnancy is safe when it is performed in gilts and sows which are already immunized against European PRRS virus via vaccination or field infection. The vaccine can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data for intramuscular injection are available in finishing pigs from 4 weeks of age onwards, which demonstrate that this vaccine can be mixed with Porcilis M Hyo.
The product literature of Porcilis M Hyo should be consulted before administration of the mixed product.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.
No information is available on the safety and efficacy of the use of Porcilis PRRS mixed with Porcilis M Hyo in breeding animals or during pregnancy.

4.9 Amounts to be administered and administration route

Reconstitute the vaccine with the corresponding adjuvanting diluent (use only Diluvac Forte).

Number of doses per vial	**Volume (ml) of diluent needed for**	
	intramuscular injection	**intradermal application**
10	20	2
25	50	5
50	100	10
100	200	20

Dosage:

Intramuscular injection: 2 ml in the neck.
Intradermal application: 0.2 ml on top or to the left or right side of the neck, or along the muscles of the back, using an intradermal device.
A small, transient, intradermal lump observed after the intradermal application is indicative of the appropriate vaccination technique.

Vaccination scheme:

A single dose is given to pigs from 2 weeks of age onwards.
Finishing pigs: a single vaccination is sufficient for protection until slaughter.
Breeding pigs: For gilts a (re)vaccination 2-4 weeks before mating is recommended.
To maintain a high and homologous level of immunity, revaccination at regular intervals is recommended, either before each next gestation or at random at 4 month intervals.
Pregnant sows should only be vaccinated after previous exposure to European PRRS virus.

It is advised to vaccinate all target pigs within a herd from the earliest recommended age onwards.
Maternally derived antibodies may interfere with the response to vaccination.
Newly introduced PRRS virus-naïve animals (e.g. replacement gilts from PRRS virus-negative herds) should be vaccinated prior to pregnancy.

The vaccine may be reconstituted shortly before vaccination for simultaneous use with Porcilis M Hyo in finishing pigs from 4 weeks of age and the following instructions should be used:

Porcilis PRRS		Porcilis M Hyo
10 doses	+	20 ml
25 doses	+	50 ml
50 doses	+	100 ml
100 doses	+	200 ml

A single dose (2 ml) of Porcilis PRRS mixed with Porcilis M Hyo is given intramuscularly in the neck.

Use sterile syringes and needles or clean intradermal equipment.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
The effects seen after a ten-fold overdose of vaccine virus and a two-fold overdose of diluent were similar to those seen after a single dose of vaccine.

4.11 Withdrawal period(s)
Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Pig, live PRRS viral vaccine,
ATCvet code: QI09AD03

Intramuscular or intradermal administration of Porcilis PRRS results in the production of specific antibodies and active immunisation against infection caused by European strains of Porcine Reproductive and Respiratory Syndrome virus. Immunity is enhanced by the adjuvant α-tocopheryl included in the diluent for reconstitution.
On the basis of antibodies induced by vaccination, it is not possible to discriminate vaccinated animals from those naturally infected with European strains of PRRS virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Freeze-dried vaccine:
culture medium,
chemically defined stabiliser CD#279 (patented)

Solvent (Diluvac Forte):
polysorbate 80,
sodium chloride,
potassium dihydrogen phosphate,
disodium phosphate dihydrate,
simethicone,
water for injection

6.2 Incompatibilities
Do not mix with any other veterinary medicinal product, except the diluent supplied with the product or with Porcilis M Hyo.

6.3 Shelf life
Shelf life of the veterinary medicinal product as packaged for sale.
Freeze-dried vaccine:
2 years
Diluent:
In glass vials 4 years, in PET vials 2 years
Shelf life after reconstitution according to directions: 3 hours at room temperature.
After mixing with Porcilis M Hyo: 1 hour at room temperature.

6.4 Special precautions for storage
Vaccine or combined packaging: store in a refrigerator (2 °C – 8 °C) . Protect from light
Diluent: store below 25 °C.

6.5 Nature and composition of immediate packaging

Vaccine container:
Glass Type I vial (Ph.Eur.), closed with a halogenobutyl rubber stopper (Ph.Eur.) and sealed with a coded aluminium cap.

Diluent container:
Glass Type II vial (Ph.Eur.) or PET-flask, closed with a halogenobutyl rubber stopper (Ph.Eur.) and sealed with a coded aluminium cap.

IM presentation:
Solvent may be packed together with the lyophilisate or separately:
Cardboard boxes with 1 or 10 glass vials with 10, 25, 50 or 100 doses of freeze-dried vaccine
Cardboard boxes with 1 or 10 glass or PET vials with 20, 50, 100 or 200 ml of Diluvac Forte
Cardboard boxes with 1 or 10 glass vials with 10, 25, 50 or 100 doses of freeze-dried vaccine plus 1 or 10 glass or PET vials with 20, 50, 100 or 200 ml of Diluvac Forte

ID presentation:
Cardboard boxes with 1 or 5 glass vials with 10, 25, 50 or 100 doses of freeze-dried vaccine plus 1 or 5 glass or PET vials with 2, 5, 10 or 20 ml of Diluvac Forte.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
represented by the national Intervet company in the Concerned Member States.

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First date of registration: 24.02.2000
End of initial MRP: 21.09.2000
MRP renewal date: 21.09.2005

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable