SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Persovac lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substance:
Live porcine reproductive and respiratory syndrome (PRRS) virus strain P120: 4.0 – 7.3 $\log_{10}$ $CCID_{50}$*

*$CCID_{50}$ Cell culture infective dose 50%

Excipient:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection
Lyophilisate: off-white, homogeneous pellet.
Solvent: clear aqueous solution.
The reconstituted product is a white, opalescent liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (for fattening)

4.2 Indications for use, specifying the target species

For active immunisation of pigs from 3 weeks of age in a PRRS virus contaminated environment, in order to reduce viraemia associated with European PRRS virus strains (genotype 1) infection.

Onset of immunity: 3 weeks post vaccination
Duration of immunity: 24 weeks post vaccination

In a laboratory trial in seronegative piglets vaccinated at the age of 32 days, a reduction of titre and overall nasal shedding was observed after a challenge 5 weeks after vaccination.

4.3 Contraindications

Do not use in PRRS naïve herds in which the presence of PRRSV has not been established using reliable diagnostic methods.
Do not use in boars producing semen, as PRRS virus can be shed in semen.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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 strain is excreted and thus may infect the susceptible pigs in contacts with vaccinated animals for at least 7 weeks. To avoid this infection, it is advised to vaccinate all target pigs within a herd from the earliest recommended age onwards.
Special precautions should be taken to avoid spreading of the vaccine strain to susceptible (seronegative) pregnant animals (see section 4.7).

Special precautions to be taken by the person administering the veterinary medicinal product to animals
None

4.6 Adverse reactions (frequency and seriousness)

Local reaction below 5 cm in diameter with associated redness is common and resolves spontaneously within 1 day. Upon intramuscular administration slight transient increases (up to 1.1°C) in rectal temperatures occurred very commonly in the studies. Temperatures return to the normal range without additional treatment, 1 to 3 days after the maximum temperature increase is observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy:
No information is available on the efficacy in pregnant animals.
The vaccine strain has been shown to be safe in seropositive pregnant animals.
It was shown that the vaccine virus, which is a European field isolate, can cross the placenta in seronegative gilts.
Exposure of the vaccine strain to susceptible (seronegative) gilts/sows should be avoided.

Lactation:
No information is available on the use of the vaccine during lactation period.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except its solvent 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.

4.9 Amounts to be administered and administration route

For intramuscular administration.
Vaccination of pigs from 3 weeks of age onwards with a single dose of 1 ml.

Reconstitute the vaccine aseptically. Use sterile syringe and needle. Avoid the introduction of contamination during reconstitution and usage.

To reconstitute the vaccine, part of the solvent (Vaccesol) is transferred to the vial containing the freeze dried pellet. After reconstitution of the pellet, the reconstituted material is transferred back to the solvent bottle. Gently shake the solvent bottle to homogenise the vaccine. The vaccine is then ready to use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

After administration of a 10-fold overdose, no adverse reactions other than those mentioned under adverse reactions were observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for suidae.
ATC vet code: QI09AD03.
No information is available regarding potential immunosuppressive properties of the vaccine virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Casein hydrolysate
Mannitol
Povidone
Sucrose
Potassium dihydrogen phosphate
Dipotassium phosphate
Potassium glutamate monohydrate
Bovine serum albumin fraction V

Solvent (Vaccesol):
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except for the solvent (Vaccesol) supplied for use with the veterinary medicinal product.

6.3 Shelf life

Shelf life of the lyophilisate as packaged for sale: 1 year
Shelf life of the solvent as packaged for sale: 3 years
Shelf life after reconstitution according to directions: 6 hours

6.4 Special precautions for storage

Lyophilisate:
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent, reconstituted product:
Store below 25 °C.
Do not freeze.

6.5 Nature and composition of immediate packaging

Lyophilisate:
10 ml, type I colourless glass vial, with bromobutyl closure and aluminium cap, containing 50 or 100 doses. Single or 10 vials in a cardboard box.

Solvent:
50 ml or 100 ml in polypropylene bottle with silicone coated polypropylene stopper and aluminium cap or in low density polyethylene bottle, with silicone coated bromobutyl stopper and aluminium cap. Single or 5 bottles in a cardboard box.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
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Buckinghamshire
HP7 9FB

8. MARKETING AUTHORISATION NUMBER

Vm 15052/4153

9. DATE OF FIRST AUTHORISATION

26 February 2020

10. DATE OF REVISION OF THE TEXT

February 2020

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