ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Vaccine box label, 50 doses, 100 doses, 10 x 50 doses, 10 x 100 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Persovac lyophilisate and solvent for suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Live PRRS virus strain P120 4.0 – 7.3 $\log_{10}$ $CCID_{50}$ / dose

3. PHARMACEUTICAL FORM

lyophilisate and solvent for suspension for injection

4. PACKAGE SIZE

50 doses
100 doses
10 x 50 doses
10 x 100 doses

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use and disposal.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 6 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4153

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vaccine vial label, 50 doses, 100 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Persovac lyophilisate and solvent for suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

PRRS virus 4.0 – 7.3 $\log_{10}$ $CCID_{50}$ / dose

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 doses
100 doses

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Solvent label, 50 ml, 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaccesol

2. STATEMENT OF ACTIVE SUBSTANCES

water for injection

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.
Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4153

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Persovac lyophilisate and solvent for suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

Manufacturer responsible for batch release:
Ceva-Phylaxia Co. Ltd.
1107 Budapest, Szállás u. 5.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Persovac lyophilisate and solvent for suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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%

Lyophilisate: off-white, homogeneous pellet.
Solvent (Vaccesol): clear aqueous solution.

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (for fattening)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

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 freezedried 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.

The reconstituted product is a white, opalescent liquid.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 6 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.
No information is available regarding potential immunosuppressive properties of the vaccine virus

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

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.

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.

Overdose (symptoms, emergency procedures, antidotes):
After administration of a 10-fold overdose, no adverse reactions other than those mentioned under adverse reactions were observed.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MM/YYYY

15. OTHER INFORMATION

Lyophilisate: 10 ml glass vial containing 50 or 100 doses. Single or 10 vials in a cardboard box.

Solvent: 50 ml or 100 ml in polypropylene or low density polyethylene bottle. Single or 5 bottles in a cardboard box.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.

Approved 26 February 2020