ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE
Inner vial cartons 10, 25, 50, 125 doses
Outer vial cartons 10 x 10, 25, 50, 125 doses
Inner sachet carton 50 doses
Outer sachet carton 10 x 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M.hyo – Parasuis, suspension for injection for pigs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated *Mycoplasma hyopneumoniae* and *Haemophilus parasuis* vaccine.
M. hyopneumoniae, strain P-5722-3 (RP* 1 – 1.9); *H. parasuis* serotype 4, strain 2170B (RP* 1 – 8.1) and serotype 5, strain IA84-29755 (RP* 1 – 3.4); Carbopol 941 and Thiomersal per 2 ml dose.
* Relative potency as compared to a reference in an in-vitro ELISA assay

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

Inner vial cartons 10, 25, 50, 125 doses
Outer vial cartons 10 x 10, 25, 50, 125 doses
Inner sachet carton 50 doses
Outer sachet carton 10 x 50 doses

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

For the active immunisation of pigs to reduce lung lesions caused by *Mycoplasma hyopneumoniae* and to reduce lesions and clinical signs caused by *Haemophilus parasuis* serotypes 4 and 5.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use contents immediately

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated at 2°C – 8°C.
Store protected from light in the original container.
Do not freeze.

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

Read the package leaflet before use.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4138

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial labels 50, 125 doses
Sachet label 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M.hyo – Parasuis, suspension for injection for pigs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated adjuvanted vaccine *M. hyopneumoniae*, strain P-5722-3; *H. parasuis* serotype 4, strain 2170B and serotype 5, strain IA84-29755; Carbopol 941 and Thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

Vial labels 50, 125 doses
Sachet label 50 doses

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use contents immediately

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated at 2°C – 8°C.
Store protected from light in the original container.
Do not freeze.

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

Read the package leaflet before use.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4138

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial labels 10 or 25 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M.hyo – Parasuis, suspension for injection for pigs.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated adjuvanted vaccine *M. hyopneumoniae*; *H. parasuis* serotype 4 and serotype 5.

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

Vial labels 10 or 25 doses

4. ROUTE(S) OF ADMINISTRATION

Suspension for injection.

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use contents immediately

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

Package leaflet
Suvaxyn M.hyo – Parasuis, 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
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer and manufacturer for the batch release:
Zoetis Manufacturing & Research Spain, S.L
C/Camprodon s/n "La Riba"
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M.hyo – Parasuis, suspension for injection for pigs.

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

Inactivated adjuvanted vaccine containing *M. hyopneumoniae*, strain P-5722-3, RP* 1 – 1.9 and
H. parasuis serotype 4, strain 2170B, RP* 1 – 8.1 and serotype 5, strain IA84-29755, RP* 1 – 3.4 per 2 ml dose. Also contains Carbopol 941 as adjuvant, thiomersal as preservative and amaranth as a colourant.

* Relative potency as compared to a reference in an in-vitro ELISA assay.

Semi-transparent, homogeneous, pale red solution.

4. INDICATIONS

For the active immunisation of pigs to reduce lung lesions caused by *Mycoplasma hyopneumoniae* and to reduce lesions and clinical signs caused by *Haemophilus parasuis* serotypes 4 and 5.

Onset of immunity against *Mycoplasma hyopneumoniae* has been demonstrated one week after second vaccination.

Onset of immunity against *Haemophilus parasuis* serotype 4 and 5 has been demonstrated 3.5 weeks after second vaccination.
Duration of immunity studies indicate that the vaccine protects for 6 months after the second vaccination against *Mycoplasma hyopneumoniae* and *Haemophilus parasuis* serotypes 4 and 5.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS*

Vaccinated animals may very commonly experience a mild injection site reaction (up to 3.7 cm in diameter) which resolves within 15 days. In rare occasions, injection site reactions of more than 9 cm in diameter, or persisting more than 15 days, may be observed.

Vaccinated animals may very commonly have a mild, transitory hyperthermia which returns to normal within 24 hours. In rare occasions hyperthermia can be observed for a longer period of time.

In very rare cases, anaphylactic reactions may be observed after vaccination.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

* The frequency of possible adverse effects is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

7. TARGET SPECIES

For pigs.

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

The vaccine should be shaken well before use.
Administer a 2.0 ml dose by intramuscular injection only. Second vaccination should be administered preferably at the alternate side of the neck.

Vaccination Schedule:

Pigs can be vaccinated from the age of 7 days and older. A second vaccination should be given 14-21 days later.
Feeder-finishing pigs should preferably be vaccinated before the age of 10 weeks when the pigs are most susceptible.
Susceptible breeding animals should be vaccinated with two doses given 2 to 3 weeks apart, prior to introduction into a herd

9. ADVICE ON CORRECT ADMINISTRATION

It is good practice to allow vaccine to warm to body temperature in the hand or pocket before administration, to avoid the discomfort of injection of a cold liquid.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport refrigerated at 2°C – 8°C.
Store protected from light in the original container.
Do not freeze.

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL WARNING(S)

The efficacy of the *H. parasuis* components of the vaccine may be reduced due to maternal antibody (MDA) interference.

Field studies have shown that maternal antibody titres to *H. parasuis* have dropped significantly in most cases by 3 weeks of age.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided on a case by case basis.

Only healthy animals should be vaccinated.

Feeder-finishing pigs should preferably be vaccinated before the age of 10 weeks when the pigs are most susceptible.

Susceptible breeding animals should be vaccinated with two doses given 2 to 3 weeks apart, prior to introduction into a herd.

Do not use during pregnancy or lactation.

After administration with a double dose, reactions in pigs are similar to those seen after administration of a single dose but injection site reactions may persist for longer (very commonly up to more than 14 days), and may be larger.

Do not mix with any other veterinary medicinal product.

In the case of accidental self-injection, seek medical advice and show the package insert or the label to the physician

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

To be completed nationally.

FOR ANIMAL TREATMENT ONLY

ATCVet code

QI09AB17

PACKAGE QUANTITIES

Box with 1 or 10 high density polyethylene vials: Containers: 25 ml vial containing 10 doses; 60 ml vial containing 25 doses; 120 ml vial containing 50 doses; 250 ml vial containing 125 doses. Box with 1 or 10 low density polyethylene sachets: 100 ml sachet containing 50 doses.

Not all pack sizes may be marketed.

LEGAL CATEGORY

To be supplied only on veterinary prescription

Approved 25 October 2019