ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Parvo/E-Amphigen, emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Inactivated Porcine Parvovirus, strain S-80	HI ≥ 94.1
Inactivated *Erysipelothrix rhusiopathiae*, serotype 2, strain B-7	RP 1-13.5

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

1 x 20 ml (10 doses)
1 x 50 ml (25 doses)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

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 the package leaflet.

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

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4205

17. MANUFACTURER'S BATCH NUMBER

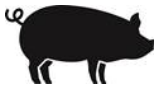
Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

HDPE vials (10 and 25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Parvo/E-Amphigen



2. QUANTITY OF THE ACTIVE SUBSTANCES(S)

Inactivated Porcine Parvovirus	HI ≥ 94.1
Inactivated *E. rhusiopathiae*	RP 1-13.5

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

10 doses (20 ml)
25 doses (50 ml)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Suvaxyn Parvo/E-Amphigen Emulsion 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 authorization holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Parvo/E-Amphigen
Emulsion for injection for pigs

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

Each dose (2 ml) contains:

Active substances:

Inactivated Porcine Parvovirus, strain S-80	HI ≥ 94.1*
Inactivated *Erysipelothrix rhusiopathiae*, serotype 2, strain B-7	RP 1-13.5**

Adjuvant:

Amphigen Base (liquid paraffin and soy lecithin)***	23,1 mg
Drakeol (liquid paraffin)	64.5 mg

Excipients:

Thiomersal	0.2 mg

*Geometric mean of the hemagglutination inhibiting antibody titers obtained after the vaccination of rabbits with one dose of a ½ dilution of the vaccine to be tested
**Relative potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs
***Of which 60% (13.875 mg) is liquid paraffin and 40% (9.25 mg) is soy lecithin.

Appearance of the veterinary medicinal product: White liquid.

4. INDICATION(S)

For active immunisation of non-pregnant sows and gilts to reduce the incidence of fever and of sudden death caused by *Erysipelothrix rhusiopathiae* infections (serotypes 1 and 2), to reduce the incidence of the diamond skin lesions caused by *Erysipelothrix rhusiopathiae* infections (serotype 2) and to reduce the transplacental infection and the associated reproductive disorders (reproductive failure due to foetal death, characterized by increased number of mummified foetuses) caused by Porcine Parvovirus (PPV).

Onset of immunity (PPV): Vaccination of breeding sows and gilts before pregnancy according to the schedule described in section 8 results in reduction of PPV transplacental infection during the second third of pregnancy.

Onset of immunity (*E. rhusiopathiae*): from 3 weeks after completion of the primary vaccination.

Duration of immunity (PPV and *E. rhusiopathiae*): 6 months after completion of the primary vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient increase in rectal temperature, around 0.5-1°C was very commonly observed (commonly up to 2.3°C) within the first 4-6 hours after vaccination in the field safety studies. This resolved within 1 day after vaccination.

Anorexia was commonly observed and depression was uncommonly observed after vaccination in the field safety studies. These resolved spontaneously without treatment.

Local reactions in the form of a visible swelling, which may present redness and increased local temperature, of up to a maximum diameter of 6 cm were very commonly observed in the field safety studies. These reactions lasted for a maximum of 4 days.

Hypersensitivity reactions have been reported very rarely based on post marketing safety experience.

The frequency of possible adverse effects 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.

Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Pigs.

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

Intramuscular use, in the neck behind the ear.
Administer one dose of 2 ml in gilts from 5 months of age and in sows, according to the following schedule:

Primary vaccination:

Gilts:
First injection: approximately 6 weeks prior to insemination.
Second injection: approximately 3 weeks prior to insemination.

Sows:
First injection: approximately 3 weeks prior to insemination.
Second injection: approximately 1 day prior to insemination.

Re-vaccination:

One injection approximately 3 weeks prior to subsequent insemination, and no later than 6 months after previous vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before administration and intermittently during the process of vaccination. The vaccine is to be administered aseptically.
The use of a multi-dosing syringe is recommended. Use vaccination devices according to the
manufacturer's instructions.

10. WITHDRAWAL PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial after EXP.
Shel life after first opening the container: use immediately

12. SPECIAL WARNING(S)

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy and lactation:
There is no information on the safety of this vaccine during pregnancy in sows. Therefore, the use is not recommended during pregnancy. The vaccine can be used during lactation.

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. 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):
No adverse reactions other than those mentioned in section 6 were observed after the administration of a 2-fold vaccine dose.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Medicines should not be disposed of via wastewater or household waste. 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

September 2021

15. OTHER INFORMATION

The vaccine contains inactivated Porcine Parvovirus and inactivated *Erysipelothrix rhusiopathiae* (serotype 2). It is intended to stimulate active immunity against Porcine Parvovirus and *Erysipelothrix rhusiopathiae* (serotypes 1 and 2) in gilts and sows.

Cardboard box of 1 vial of 20 ml (10 doses).

Cardboard box of 1 vial of 50 ml (25 doses).

Not all pack sizes may be marketed.

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

Approved: 30/09/21