ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL 50 ml (25 doses) and CARDBOX 2x50 ml (2x25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUVAXYN® Parvo/E

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml

Active substances:

Inactivated porcine parvovirus, strain S-80:	Inducing an HIA* titre of at least 160 (in rabbits)
Inactivated *Erysipelothrix rhusiopathiae,* strain B-7 (serotype 2):	RP** ≥ 1.8 in accordance with the EP Monograph

*HIA: haemagglutination inhibiting antibody
**Relative Potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs

Adjuvants:

Marcol 52:	730.14 mg
Montanide 888:	74.32 mg
Simulsol 5100:	69.95 mg

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

25 doses
2x25 doses

5. TARGET SPECIES

Pigs (gilts and sows)

6. INDICATION(S)

For the active immunisation of pigs (gilts and sows) to:
Prevent reproductive disorders caused by porcine parvovirus.
Reduce clinical signs caused by *Erysipelothrix rhusiopathiae* infections, serotype 2 and serotype 1.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

One dose of 2 ml per animal by intramuscular use in the neck.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use immediately

11. SPECIAL STORAGE CONDITIONS

Store and transport at 2ºC - 8ºC. Do not freeze. Protect from light.

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

Any unused product or waste material should be disposed of in accordance with national requirements

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

Vm 42058/4141

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial 20 ml (10 doses) and Cardbox 20 ml (10 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUVAXYN® Parvo/E

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose of 2 ml
Inactivated porcine parvovirus, strain S-80: Inducing an HIA* titre of at least 160 (in rabbits)
Inactivated *Erysipelothrix rhusiopathiae,* strain B-7 (serotype 2): RP** ≥ 1.8 in accordance with the EP Monograph
*HIA: haemagglutination inhibiting antibody
**Relative Potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs

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

10 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular route

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Batch {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

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 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® Parvo/E

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

Per dose of 2 ml

Active substances:
Inactivated porcine parvovirus, strain S-80: Inducing an HIA* titre of at least 160 (in rabbits)
Inactivated *Erysipelothrix rhusiopathiae,* strain B-7 (serotype 2): RP** ≥ 1.8 in accordance with the EP Monograph
*HIA: haemagglutination inhibiting antibody
**Relative Potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs

Adjuvants:

Marcol 52:	730.14 mg
Montanide 888:	74.32 mg
Simulsol 5100:	69.95 mg

4. INDICATION(S)

For the active immunisation of pigs (gilts and sows) to:
Prevent reproductive disorders caused by porcine parvovirus.
Reduce clinical signs caused by *Erysipelothrix rhusiopathiae* infections, serotype 2 and serotype 1.

5. CONTRAINDICATIONS

Do not use less than 3 weeks before mating.

6. ADVERSE REACTIONS

Following first vaccination transient hyperthermia up to 1ºC above normal for up to 24 hours after vaccination in up to 25% of pigs.
Local tissue reactions in the form of visible swelling (granulomas) at the injection sites may occur in 33% of the vaccinated animals for up to16 days. The area of reaction can be diffuse and reach 2-5 cm in diameter.

Following second vaccination transient hyperthermia up to 1ºC above normal for 24-48 hours after vaccination in up to 40% of pigs.
Local tissue reactions in the form of mild diffuse visible swelling (granulomas) at the injection sites may occur in 92% of the vaccinated animals at least 14 days in 25% of the pigs reacting. The area of reaction can vary from 5 cm to 10 cm in diameter.

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

7. TARGET SPECIES

Pigs (gilts and sows)

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

One dose of 2 ml per animal by intramuscular use in the neck.

Vaccination Schedule:
-Primary Vaccination:
Gilts from 5 months of age and sows: Two injections 3-4 weeks apart. The second dose should be given at least 4 weeks before mating.

-Revaccination:
One dose during each lactation period 3 to 4 weeks before mating.

9. ADVICE ON CORRECT ADMINISTRATION

The vaccine is to be administered aseptically. Shake well before administration and intermittently during the process of vaccination

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport at 2ºC - 8ºC. Do not freeze. Protect from light.
Keep out of the reach and sight of children.

Do not use after the expiry date stated on the label and carton.

Shelf-life after first opening the container: use immediatetly.

12. SPECIAL WARNING(S)

Special precautions for use in animals
- Avoid stress in the animals around the time of vaccination.
- Administer only to animals in good health condition

Special precautions to be taken by the person administering the veterinary medicinal product to animals
To the user:
This 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 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 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.

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

Any unused product or waste material should be disposed of in accordance with national requirements.
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

November 2019

15. OTHER INFORMATION

Do not use in pregnant sows

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.

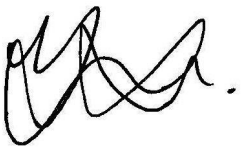
Do not mix with any other vaccine/immunological product.

An overdose of the product can result in transient hyperthermia of 1-2°C above normal for 24 hours after vaccination in 80% of pigs.
Local tissue reactions in the form of visible swelling (granulomas) in the majority of vaccinated pigs for at least 28 days. The area of reaction can be diffuse from 5 to 10 cm in diameter.

20 ml Type I hydrolytic glass vials containing 10 doses and 50 ml Type II hydrolytic glass vials containing 25 doses, with butyl elastomer stoppers and aluminium seals.
Package sizes: carton box with 1 glass vial of 20 ml and carton box with two vials of 50 ml.

Not all pack sizes may be marketed.

For animal treatment only - to be supplied only on veterinary prescription.



Approved: 10 December 2019