SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUVAXYN® Parvo/E

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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 (Mineral oil)	730.14 mg
Montanide 888 (Emulsifier)	74.32 mg
Simulsol 5100 (Emulsifier)	69.95 mg

Excipients:

Thiomersal	0.2 mg
Formaldehyde	≤0.05%

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection
Appearance: Ivory white oil emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (gilts and sows).

4.2 Indications for use, specifying the target species

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.
The onset of immunity starts 3 weeks after vaccination and duration of the protection is 6 months.

4.3 Contraindications

Do not use less than 3 weeks before mating.

4.4 Special warnings <for each target species>

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

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

(ii) 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Pregnancy: Do not use in pregnant sows
Lactation: No special precautions

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. 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

One dose of 2 ml per animal by intramuscular use in the neck.
The vaccine is to be administered aseptically. Shake well before administration and intermittently during the process of vaccination

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.

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

An overdose of the product can result in transient hyperthermia of 1-2ºC 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.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against porcine parvovirus and *Erysipelothrix rhusiopathiae*, serotype 2 and serotype 1.
ATCVet code QI09AL01.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Formaldehyde
Gentamicin

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf life

15 months.
Following broaching of the vial the vaccine should be used immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

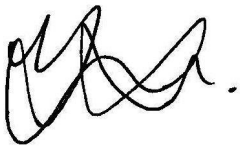
Vm 42058/4141

9. DATE OF FIRST AUTHORISATION

23 April 2002

10. DATE OF REVISION OF THE TEXT

November 2019



Approved: 12 November 2019