

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Parvo ST suspension for intramuscular injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	<u>Quantitative composition (2 ml dose)</u>
Active substances:	
Inactivated porcine parvovirus, strain NADL-2	Antibody titre by Haemagglutination Inhibition (HI) in vaccinated rabbits \geq 368 GMT*
Adjuvant:	
Carbopol #941	2.0 mg
Excipients:	
Thiomersal	0.17 mg
* Geometric Mean Titre	
For the full list of excipients, see section 6.1	

3 PHARMACEUTICAL FORM

Suspension for injection.
Clear pink suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs of a minimum age of 6 months (gilts and sows).

4.2 Indications for use, specifying the target species

Active immunisation of sows and gilts to reduce transplacental infection of progeny with porcine parvovirus.

Onset of immunity: 8 weeks after primary vaccination.
Duration of immunity: 4 months after primary vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

In case of a return to service, a booster vaccination should be considered.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only clinically healthy animals.

Avoid stress in the animal around the time of injection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Mild, transient local reactions, including slight visible redness, and slight visible/palpable swelling (< 2 cm) were observed in approximately 50% of pigs treated. Up to 15% of vaccinated animals may have a mild increase in body temperature ($\geq 1^{\circ}\text{C}$) at 4 hours after vaccination. All reactions disappeared within 24 hours.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy. Therefore the vaccine should not be used during pregnancy.

Can be used in lactating animals.

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

Administration route: intramuscular

Dosage: 1 dose = 2 ml

The use of a multi-dosing syringe (injector) is recommended.

Primary vaccination (gilts of 6 months of age or older): A single dose, administered at least 14 days prior to mating.

Re-vaccination: A single dose during each lactation period. The recommended interval between vaccination and mating is 14 days.

Administration:

Shake the vial well before and during use. Vaccinate only intramuscularly in the neck behind the ear.

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

After administration of two-fold of the maximum dose by the recommended route, an increase in frequency of local reactions up to 79% of vaccinated pigs can be observed.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against porcine parvovirus.

Pharmacotherapeutic group: Inactivated viral vaccines.

ATC vet code: QI09AA02

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol #941
Thiomersal
Sodium chloride
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

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

Shelf life after first broaching the immediate packaging: Use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

6.5 Nature and composition of immediate packaging

High density polyethylene vials containing 10 doses (20 ml) or 50 doses (100 ml), with chlorobutyl stoppers and aluminium caps.

Package sizes: Carton boxes with 1 or 10 vials of either 20 ml (10 doses) or 100 ml (50 doses).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/097/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th August 2008

Date of last renewal: 28th August 2013

10 DATE OF REVISION OF THE TEXT

January 2014