

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10861/050/001**

Case No: 7003442

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 of 2007) hereby grants to:

Fort Dodge Animal Health Limited

Flanders Road, Hedge End, Southampton SO30 4QH, United Kingdom

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Suvaxyn Parvo

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **23/10/2007**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Parvo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	<u>Per dose (2 ml)</u>
<u>Active substance:</u>	
Porcine Parvovirus (strain NADL-2, PPV-PK-7)	$10^{6.8}$ TCID ₅₀ *
<u>Adjuvant:</u>	
Carbopol 941	2.00 mg
<u>Excipients:</u>	
<u>Preservative</u>	
Thiomersal	0.17 mg

* 50% Tissue Culture Infective Dose, prior to inactivation

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Gilts and sows aged six months or greater.

4.2 Indications for use, specifying the target species

For active immunisation of gilts and sows to reduce parvovirus related still birth, foetal mummification and embryonic death.

The onset of immunity is approximately 5 weeks with the duration of immunity being approximately 6 months.

4.3 Contraindications

Do not vaccinate sick animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Avoid stress in the animal around the time of injection.

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

Avoid accidental self-injection or ingestion. Wash injected area or drink water if ingested. Seek medical advice if symptoms develop following self-administration/ingestion and show the package insert or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not to be used during pregnancy but can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from concurrent use of this vaccine with any other. It is therefore recommended that no other vaccine should be administered within 14 days before or after vaccination with Suvaxyn Parvo.

4.9 Amounts to be administered and administration route

Dosage: 1 dose = 2ml.

The use of a multi-dosing syringe is recommended.

Basic vaccination scheme:

Gilts: Gilts should receive the first vaccination at 6 months of age or older and at least two weeks prior to mating.

Re-vaccination scheme:

Sows: Vaccinate during each lactation period, or every 6 months between pregnancies. The recommended interval between vaccination and mating for sows is 2 weeks.

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

None.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Porcine Parvovirus.

ATC Code: Q109AA02

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol 941
Thiomersal
Sodium chloride
Water for Injection

6.2 Incompatibilities

Do not mix with any other immunological product.

6.3 Shelf-life

18 months.
Do not keep broached vials longer than 8 hours.

6.4 Special precautions for storage

Store at +2 to +8°C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Nature: Polyethylene bottles
Contents: 20 or 100ml
Pack size: 1 x 20 ml, 1 x 100ml

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

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

7 MARKETING AUTHORISATION HOLDER

Fort Dodge Animal Health
Flanders Road
Hedge End
Southampton
SO30 4QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA No. 10861/50/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd October 2002
23rd October 2007