

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10861/085/001**

Case No: 7001230

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

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 Ery

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.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: 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® Ery

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2 ml

Active substances:

Inactivated *Erysipelothrix rhusiopathiae*, RP* ≥ 1.8 in accordance with
strain B-7 (serotype 2): the EP Monograph

* Relative Potency compared to a reference serum obtained from a vaccine that has given satisfactory protection in vaccinated pigs.

Adjuvant(s):

Marcol 52 (Mineral oil) 730.14 mg

Montanide 888 (Emulsifier) 74.32 mg

Simulsol 5100 (Emulsifier) 69.95 mg

Excipients:

Thiomersal (Preservative) 0.2 mg

Formaldehyde $\leq 0.05\%$

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:

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

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 insert 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 1°C 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 to 16 days. The area of reaction can be diffuse and reach 2-5 cm in diameter.

Following second vaccination transient hyperthermia up to 1°C above normal for 24-48 hours after vaccination in up to 60% of pigs as maximum

Local tissue reactions in the form of visible swelling (granulomas) at the injection sites may occur in 90% of the vaccinated animals for up to 10 days. The area of reaction can be diffuse and reach 2-5 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 from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

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

A twofold 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 up to 80% of pigs lasting for up to 16 days. Only in exceptional cases local tissue reactions could be for up to 30 days after vaccination. The area of reaction can be diffuse and reach 2-5 cm in diameter.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code QI09AB03.

To stimulate active immunity against *Erysipelothrix rhusiopathiae*, serotype 2 and serotype 1. The strain of *Erysipelothrix rhusiopathiae* used in the formulation of the vaccine is serotype 2 and it also cross protects against serotype 1 infections.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Marcol 52 (Mineral oil)
Montanide 888 (Emulsifier)
Simulsol 5100 (Emulsifier)
Thiomersal (Preservative)
Formaldehyde

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

1 year.
Following broaching of the vial the vaccine should be used in 2 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

50 ml Type II hydrolytic glass vials containing 25 doses, with bromobutyl elastomer stoppers and aluminium seals.
Package sizes: carton box with two vials of 50 ml.

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 national requirements.

7 MARKETING AUTHORISATION HOLDER

Fort Dodge Veterinaria, S.A.
Ctra. Camprodon, s/n
17813 Vall de Bianya (Gerona)
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10861/085/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th May 2003

10 DATE OF REVISION OF THE TEXT

28th June 2007