Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Erysorb Plus

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	per ml
Formalin killed cells of the *Erysipelothrix rhusiopathiae* serotype 2 of the following strains:	
CN3342	at least 3.3 x 10^8 cells*
CN3461	at least 3.3 x 10^8 cells*
and formalin killed cells of *Erysipelothrix rhusiopathiae* serotype 1 of the following strain:	
P15/10	at least 3.3 x 10^8 cells*
* together inducing at least 50IU/dose	
Other constituents:	
Aluminium Hydroxide	350 mg
Tris	2.42 mg
Maleic acid	2.32 mg
Sodium chloride	8.5 mg
Formaldehyde	<0.5 mg
Thiomersal	0.13 mg
Purified Water	to 1 ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Sows, gilts and finishing pigs

4.2 Indications for use, specifying the target species

The vaccine contains inactivated erysipelas antigens of two serotypes, to stimulate both active immunity in the vaccinated animals and passive immunity in their progeny to aid in reducing clinical signs and lesions against Erysipelas disease.
A protective immune response is normally achieved by two weeks after the second dose of a primary vaccination course.

4.3 Contraindications

None

4.4 Special warnings for each target species

In any group of animals, a small number of individuals may fail to respond to vaccination as a result of immunological incompetence or for some other reason. Satisfactory immune responses will only be attained in healthy animals, thus it is important to avoid vaccination of animals which have intercurrent disease or which have poor nutritional status.
As with most killed vaccines, significant levels of immunity cannot be expected until 2 weeks after the second dose of the primary vaccination course.
It is recommended that all animals in a herd should be vaccinated to control the spread of the disease.
The vaccine is not recommended for the use in boars.
Stress should be avoided when vaccinating animals especially in the later stage of the pregnancy.

4.5 Special precautions for use

Special precautions for use in animals

None

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

In the case of accidental self injection seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

As with all vaccines, occasional hypersensitivity reactions may occur.

Erysorb Plus is an inactivated vaccine containing an adjuvant. Vaccination may result in transient (2-3 days duration) soft, non-painful, swellings at the injection site of up to 2 cm, particularly in pigs. Subcutaneous nodules, persisting for at least 2-3 weeks, may occur in about half the vaccinated pigs.

4.7 Use during pregnancy, lactation or lay

Erysorb Plus can be used in pregnant pigs.

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 Erysorb Plus with any other vaccine. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

The vaccine may be administered using a sterile needle and syringe, providing a fresh sterile needle is used each time the rubber cap is punctured to avoid contamination of the remaining contents.

Syringes and needles must be from gamma irradiated packs or freshly sterilised by boiling for at least 20 minutes. No alcohol or other disinfectants should be used for sterilisation.

The use of an automatic vaccinator is recommended. Since the bottle is non-collapsible, a vaccinator with a vented draw-off spike or similar device must be used. The instructions supplied with such syringes should be noted and care should be taken to ensure the delivery of the full dose, particularly with the final few doses from the bottle.

Shake vaccine bottle well before use.

Dose = 2ml by subcutaneous injection at the base of the ear, observing aseptic precautions.

Basic Vaccination:
Sows and gilts: 2ml repeated after an interval of 2-4 weeks. Pregnant sows and gilts may be vaccinated at six and three weeks prior to expected date of farrowing to provide active protection to the sows and passive protection via the colostrum to the newborn piglets against neonatal infections caused by *Erysipelothrix rhusiopathiae (Ery.insidiosa).*

Piglets from vaccinated gilts will remain immune up to at least 2 weeks of age.

Piglets from vaccinated sows:
2ml at 8 weeks of age repeated 14 days later. The immunity developed should persist until the piglets are approximately 6 months of age.

Piglets from non-vaccinated sows:
In the absence of maternal antibody, piglets may be vaccinated with a 2ml dose as early as 8 days of age with a second injection of 2ml two weeks later, to provide immunity which should provide protection against disease until 3 months of age and may provide some protection, particularly against severe signs of disease, in piglets until 6 months of age.

Re-Vaccination:
Sows: Booster doses should be given at approximately 3 weeks prior to subsequent farrowings to provide optimum passive protection via the colostrum to the newborn piglets against neonatal infections of *Erysipelothrix rhusiopathiae.* Booster injections may be given at fixed intervals of every six months to protect the sow, although if this is not prior to farrowing passive protection of their piglets may not be assured.

Finishing and other pigs: Every six months where applicable.

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

Accidental overdosage is unlikely to cause any reaction other than those described in section 4.3. No adverse local or systemic reactions were noted in overdose studies.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC code QI09AB03
To stimulate active immunity against erysipelas disease and to provide passive immunity against erysipelas disease to piglets born to fully vaccinated sows and gilts.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tris(hydroxymethyl)aminomethane
Maleic Acid
Sodium chloride
Formaldehyde
Thimerosal
Purified Water

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf-life

Unopened, the product has a 3 year shelf life.
Following withdrawal of the first dose, use the product within 8 hours.
Partly used packs must be destroyed at the end of a day's operations but no later than 8 hours after opening, as re-puncture of the rubber cap could cause contamination of the remaining contents.

6.4 Special precautions for storage

Store in a cool, dark place at +2°C to +8°C. Do not freeze. Use before the expiry date printed on the pack.

6.5 Nature and composition of immediate packaging

50ml (= 25 doses) and 100ml (= 50 doses) low density polyethylene (Ph. Eur.) bottles closed with a combination seal (aluminium cap with a rubber disc)

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

Intervet Ireland Ltd.
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/159/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th February 2002