DYNTEC spol. s r. o.

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Summary of product characteristics SUIVAC PRRS-IN emulsion for injection, vaccine for pigs

SPC

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUIVAC PRRS-IN emulsion for injection, vaccine for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each one dose (2 ml) contains:

active substance(s):

inactivated virus of PRRS (strain VD-E1, VD-E2, VD-A1) inducing antibodies ≥ 1000 EU*.
*EU: amount of antibodies determined by ELISA test after immunization of pigs under the defined conditions,

adjuvant(s):

oil emulsion	0.36 ± 0.01 ml,
saponin	NMT 0,4 mg,

excipient(s):

thiomersal	NMT 0.2 mg,
medium with immunogen	1.64 ± 0.01 ml.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection. Milky-white up to pinkish liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indication for use, specifying the target species

An active prophylactic immunization of pigs from 6 weeks of age against porcine reproduction and respiratory syndrome of pigs (PRRS).

The immunity develops within 3 weeks after primary vaccination and the full immunity is reached after 3 to 4 weeks after re-vaccination. Sufficient immunity persists for 4 to 6 months. Colostral immunity decreases in piglets in dependence on their age and it persists for approximately 2 to 3 months.

4.3 Contraindications

Do not use in animals with developed clinical signs of the disease, animals suffering from a high temperature and pregnant animals 2 weeks prior to expected farrowing.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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 against.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense welling, 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.

Other precautions

The product has no influence on the environment and does no contain substances, which react with ambient environment and clothes.

4.6 Adverse reactions (frequency and seriousness)

After administration of a vaccine, the general disorder of the health state can be rarely recorded with symptoms of somnolence, inappetence and elevation of body temperature. Sporadically, swelling and reddening at the site of administration can occur. An onset of undesirable reactions is recorded within 2 hours after administration of the vaccine, with a length of its duration being approximately 2 days. On immunization of a higher amount of animals, an incidence of moderate general reactions at frequency up to 5 % can be envisaged. To alleviate general reactions, the symptomatic treatment is advisable.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy. Owing to the immunobiological load and animal handling it is not, however, advisable to immunize 2 weeks prior to expected farrowing.

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.

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4.9 Amounts to be administered and administration route

Prior to use, the vaccine should be allowed to reach the ambient temperature and shake.

The immunization dose must be taken from the medicinal bottle and administered to an animal using an aseptic technique.

The vaccine should not be used if vial closing has been damaged.

The immunization dose per 1 animal is 2 ml, irrespective of sex and weight.

The vaccine should be administered deep intramuscularly (i.m.) at the site of the neck, behind the ear.

The basic immunization scheme is primary vaccination with re-vaccination. To guarantee a broader immunity spectrum, it is advisable to perform a second re-vaccination after 3 to 4 weeks after the first re-vaccination; in pregnant animals it is after 6 to 4 weeks prior to expected farrowing. To immunize the individual categories of pigs the following immunization schemas are recommended:

Non-immunized gilts: primary vaccination at an age of 5 to 6 months (prior to mating) with re-vaccination over 3 to 4 weeks.

Immunized gilts: re-vaccination is to be carried out 6 to 4 weeks prior to the expected farrowing.

Non-immunized sows: primary vaccination prior to mating with re-vaccination after 3 to 4 weeks.

Immunized sows: repeated re-vaccination is carried out always 6 to 4 weeks prior to the next expected farrowing. In case the period between two farrowing exceeds 10 months, it is advisable to perform primary vaccination and re-vaccination according to the above mentioned process.

Piglets: primary vaccination at an age of 6 to 10 weeks with re-vaccination after 3 to 4 weeks.

Non-immunized boars: primary vaccination at an age of 6 months (or prior to their inclusion into the herd) with the first re-vaccination after 3 to 4 weeks after primary vaccination and with following repeated re-vaccinations every 4 to 6 months. (It is possible to re-vaccinate even in shorter intervals e.g. after 3 to 4 months.)

Immunized boars: re-vaccination at an age of 6 months (or prior to the inclusion into the herd) with subsequent re-vaccinations every 4 to 6 months (It is possible to re-vaccinate even in shorter intervals e.g. after 3 to 4 months.)

At collective immunization of animal, it is advisable to primary vaccinate all animals independently on category and age with a following re-vaccination after 3 to 4 weeks.

The above-mentioned immunization schemes are only of an orientation character. The scope of immunization is at discretion of the veterinary doctor, and it also depends on a particular epizootological situation. The immunization schema can be conformed to reproductive cycle.

Specific colostral immunity may negatively influence creation of post-vaccination immunity in dependence on its level.

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

The vaccine is safe after administration of a doubled dose.

Reactions described in point 4.6 Adverse reactions (frequency and seriousness) may be observed after

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overdosage.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Veterinaria immunopraeparata.

ATC vet code: Q15AA.

Inactivated vaccine for an active prophylactic immunization of pigs from 6 weeks of age against porcine reproduction and respiratory syndrome of pigs (PRRS).

To stimulate active immunity against PRRS. The active ingredient of the product consists of inactivated strains VD-E1, VD-E2 and VD-A1 of PRRS virus bound to the adjuvant constituent of the vaccine. After parenteral administration, immunogens are being released gradually from the adjuvant constituent and stimulates immune system, inducing creation of active specific immunity against porcine reproduction and respiratory syndrome of pigs. A series of defensive mechanisms originates for inhibition of subsequent development of the disease after a contact with the infection.

With development of the specific immunity, the immunogens are gradually actively degraded and metabolized. Inactive ingredients are metabolized after the immunization of animals, degraded and excreted from the organism. The product has no influence on the environment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oil emulsion,
saponin,
thiomersal,
purified water,
sodium chloride,
potassium chloride,
potassium dihydrogen phosphate,
disodium phosphate dodecahydrate.

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: 18 months.

Shelf life after first opening the immediate packaging: 10 hours.

The shelf life is mentioned on a label of each vial and on a box.

6.4 Special precautions for storage

Storage in a refrigerator (2 °C - 8 °C).

Protect from frost. Protect from light. Store in a dry place.

6.5 Nature and composition of immediate packaging

1 x 25 doses, i.e. 50 ml in a glass or plastic medical bottle with the effective volume of 50 ml, closed with a rubber plug and an aluminum torque collar, provided with a label and placed in a carton box with package leaflet,

1 x 50 doses, i.e. 100 ml in a glass or plastic medical bottle with the effective volume of 100 ml, closed with a rubber plug and an aluminum torque collar, provided with a label and placed in a carton box with package leaflet,

1 x 250 doses, i.e. 500 ml in a glass or plastic medical bottle with the effective volume of 500 ml, closed with a rubber plug and an aluminum torque collar, provided with a label and placed in a carton box with package leaflet.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

97/001/04-C

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 26th February 2004

10. DATE OF REVISION OF THE TEXT

August 2009

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.