Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substance
Lyophilisate:
Live attenuated Porcine Respiratory and Reproductive Syndrome Virus (PRRSV), strain 94881 (genotype 1): $10^{4.4}$ -$10^{6.6}$ $TCID_{50}$*
* Tissue Culture Infectious Dose 50%

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: off-white to milky-grey
Solvent: clear, colourless solution

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the target species

For active immunisation of clinically healthy pigs from 17 days of age until the end of fattening and older from farms affected with European (genotype 1) Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) to reduce virus load in blood in seropositive animals under field conditions.

Under experimental challenge conditions in which only seronegative animals were included, it was demonstrated that vaccination reduces lung lesions, virus load in blood and lung tissues as well as negative effects of infection on daily weight gain. A significant reduction of the respiratory clinical signs could additionally be demonstrated at the onset of immunity.

Onset of immunity: 3 weeks
Duration of immunity: 26 weeks

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in breeding animals.
Do not use in PRRS naïve herds in which the presence of PRRSV has not been established using reliable diagnostic methods.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
Do not use in boars producing semen for naïve herds, as PRRSV can be shed in semen.
Maternally derived antibodies have been shown to interfere with vaccine efficacy. In the presence of maternally derived antibodies, timing of initial vaccination of piglets should be planned accordingly.

4.5 Special precautions for use

Special precautions for use in animals
The vaccine strain can spread to unvaccinated animals in contact with vaccinated animals up to 3 weeks post vaccination. Special precautions should be taken to avoid spreading of the vaccine strain within the herd, e.g. from positive to naïve animals. Vaccinated animals may excrete the vaccine strain by faecal excretion and in some cases by oral secretions.

Care should be taken to avoid spread of vaccine virus from vaccinated animals to unvaccinated animals that should remain free from PRRS virus.

For optimum PRRS control programme, all animals in a herd should be vaccinated. In the sow herd it is recommended to use a vaccine licensed for use in sows.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Slight transient increases (not greater than 1.5°C) in body temperature can be observed very commonly following vaccination. Temperatures return to normal without additional treatment, 1 to 3 days after the maximum temperature increase is observed.

Injection site reactions are uncommon. Transient minimal swelling or redness of the skin may be observed. These reactions disappear spontaneously without any additional treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interactions

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Boehringer Ingelheim's Ingelvac CircoFLEX and administered at one injection site.

The product literature of Ingelvac CircoFLEX should be consulted before administration.
In individual pigs, the temperature increase after associated use rarely exceeds 1.5 °C but stays below an increase of 2 °C. The temperature returns to normal within 1 day after the peak temperature is observed. Transient local injection site reactions, which are restricted to a slight redness, may rarely occur directly after vaccination. Reactions resolve within 1 day. Immediate mild hypersensitivity-like reactions were commonly observed after vaccination, resulting in transient clinical signs such as vomiting and rapid respiration, which resolved within a few hours without treatment. Transient purple skin discoloration was uncommonly observed and resolved without treatment. Appropriate precautions to minimise handling stress during the administration of the product may lower the frequency of hypersensitivity-like reactions.

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

Dosage and method of administration:
Intramuscular use.
Single intramuscular injection of one dose (1 ml), irrespective of body weight.

For reconstitution, transfer the entire content of the solvent vial to the vial containing the lyophilisate and reconstitute the lyophilisate as follows: 10 doses in 10 ml, 50 doses in 50 ml, 100 doses in 100 ml and 250 doses in 250 ml of the solvent.
Ensure that the lyophilisate is completely reconstituted before use.
Visual appearance after reconstitution: clear, colourless suspension.
Avoid introduction of contamination during use.
Use sterile equipment.
Avoid multiple broaching, for example by using automatic injectors.

When mixed with Ingelvac CircoFLEX:

- Vaccinate only pigs as from 17 days of age.
- Cannot be administered in pregnant or lactating pigs.

When mixed with Ingelvac CircoFLEX the following equipment should be used:

- Use the same volumes of Ingelvac CircoFLEX and Ingelvac PRRSFLEX EU.
- Ingelvac CircoFLEX hereby replaces the solvent of PRRSFLEX EU.
- Usea pre-sterilised transfer needle. Pre-sterilised transfer needles (CE certified) are commonly available via medical equipment suppliers.

To ensure correct mixing follow the steps as described below:

1. Connect one end of the transfer needle to the vaccine bottle of Ingelvac CircoFLEX.
2. Connect the opposite end of the transfer needle to the vaccine bottle of Ingelvac PRRSFLEX EU.
3. Transfer the Ingelvac CircoFLEX vaccine into the vaccine bottle of Ingelvac PRRSFLEX EU. If needed, gently press the vaccine bottle of Ingelvac CircoFLEX to facilitate the transfer. After the transfer of the full content of Ingelvac CircoFLEX, disconnect and discard transfer needle and empty vaccine bottle of Ingelvac CircoFLEX.
4. To ensure appropriate mixing of the vaccines, gently shake the vaccine bottle of Ingelvac PRRSFLEX until the cake is fully dissolved.
5. Administer one single injection dose (**1 ml**) of the mixture intramuscularly per pig, irrespective of body weight. For administration, vaccine devices should be used in accordance with the device instructions provided by the manufacturer.

Use the entire vaccine mixture within 4 hours after mixing. Any unused mixture or waste material should be disposed according to the instructions given in section 6.6.

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

No additional negative effects have been observed following the administration of a 10-fold overdose in naïve piglets of two weeks of age with regard to systemic and local reactions.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, live viral vaccines for pigs. Porcine Reproductive and Respiratory Syndrome Virus
ATCvet code: QI09AD03

The vaccine is designed to stimulate the development of an immune response in pigs to Porcine Reproductive and Respiratory Syndrome Virus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Sucrose
Gelatin
Potassium hydroxide
Glutamic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Sodium chloride

Solvent:
Phosphate buffered solution:
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate
Water for injection

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except solvent supplied for use with the veterinary medicinal product or Boehringer Ingelheim´s Ingelvac CircoFLEX (mixture not for use in pregnant or lactating pigs).

6.3 Shelf-life

Shelf life of the vaccine lyophilisate as packaged for sale: 2 years
Shelf life of the solvent as packaged for sale: 3 years
Shelf life after reconstitution with solvent according to directions: 8 hours

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

Lyophilisate:
Type I amber glass vials with bromobutyl rubber stopper and aluminium seal.

Solvent:
High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal.

1 lyophilisate vial of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses) and 1 solvent vial of 10 ml, 50 ml, 100 ml or 250 ml packed in one cardboard box.

12 lyophilisate vials of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses) packed in a separate cardboard box.

25 lyophilisate vials of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses) packed in a separate cardboard box.

12 solvent vials of 10 ml, 50 ml, 100 ml or 250 ml packed in a separate cardboard box.

25 solvent vials of 10 ml, 50 ml, 100 ml or 250 ml packed in a separate cardboard box.

Not all package sizes may be marketed.

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

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

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 April 2015
Date of last renewal: 13 March 2020

10 DATE OF REVISION OF THE TEXT

September 2021