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 1 ml dose contains:

Active substance:
Lyophilisate:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881, live attenuated:
$10^{4.4}$ - $10^{6.6}$ $TCID_{50}$*

* Tissue Culture Infectious Dose 50%

Excipients:

Qualitative composition of excipients and other constituents
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 injections

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

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each 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.

3.3 Contraindications

Do not use in 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.
Do not use in boars producing semen for naïve herds, as PRRSV can be shed in semen.

3.4 Special warnings

Vaccinate healthy animals only.
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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Vaccination should aim to achieve a homogenous immunity in the target population at farm level. In the sow herd it is recommended to use a vaccine strain licensed for use in sows.

Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd. A PRRS vaccine based on the same strain (strain 94881) and authorised for the immunisation of gilts and sows can be used on the same farm.

In order to limit the potential risk of recombination between PRRS MLV vaccine strains of the same genotype, do not use different PRRS MLV vaccines based on different strains of the same genotype on the same farm at the same time. In the case of transitioning from one PRRS MLV vaccine to another PRRS MLV vaccine, a transition period should be respected between the last administration of the current vaccine and the first administration of the new vaccine. This transition period should be longer than the shedding period of the current vaccine following vaccination.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Very common (> 1 animal / 10 animals treated):	Elevated temperature[1]
Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site reaction (injection site swelling, injection site reddening)[2]

1 Slight increase not greater than 1.5 °C, return to normal without treatment, 1 to 3 days after the maximum temperature.
2 Minimal, disappears spontaneously without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

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 except the product mentioned above. 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.

3.9 Administration routes and dosage

Intramuscular use.

Single 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.
- Use a 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 5.5.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AD03

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

5. PHARMACEUTICAL PARTICULARS

5.1 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 as mentioned in section 3.8 above. Both mixtures are not for use in pregnant or lactating pigs.

5.2 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.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 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.

Cardboard box of 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.

Cardboard box of either 12 or 25 lyophilisate vials of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses).

Cardboard box of either 12 or 25 solvent vials of 10 ml, 50 ml, 100 ml or 250 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 61700/5001
Vm 61700/3001

8. DATE OF FIRST AUTHORISATION

26 March 2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 01 December 2025