SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn Circo+MH RTU emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:	
Inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein	2.3 – 12.4 RP*
Inactivated *Mycoplasma hyopneumoniae,* strain P-5722-3	1.5 – 3.8 RP*
Adjuvant:	
Squalane	0.4% (v/v)
Poloxamer 401	0.2% (v/v)
Polysorbate 80	0.032% (v/v)
Excipients:	
Thiomersal	0.2 mg

*Relative potency unit determined by ELISA antigen quantification (*in vitro* potency test) compared to a reference vaccine.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White homogenous emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (for fattening).

4.2 Indications for use, specifying the target species

For active immunisation of pigs from 3 weeks of age against Porcine Circovirus type 2 (PCV2) to reduce viral load in blood and lymphoid tissues and fecal shedding caused by infection with PCV2.
For active immunization of pigs from the age of 3 weeks against *Mycoplasma hyopneumoniae* to reduce lung lesions caused by infection with *M. hyopneumoniae*.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 23 weeks after vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate only healthy animals.

4.5 Special precautions for use

Special precautions for use in animals
No information is available on the safety of this vaccine in breeding boars. Do not use in breeding boars.

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)

A transient increase in body temperature (on average 1 °C) was very commonly observed during the first 24 hours after vaccination in laboratory and field trials. In individual pigs the temperature increase compared to pre-treatment may commonly exceed 2 °C. This resolves spontaneously within 48 hours without treatment.
Local tissue reactions in the form of swelling at the injection site, which may be associated with local heat, redness and pain at palpation, are very common and may last for up to 2 days (based on laboratory safety studies). The area of local tissue reactions is in general below 2 cm in diameter. In a laboratory study, a post-mortem examination of the injection site, performed 4 weeks after the administration of a repeated single dose of the vaccine, very commonly revealed a mild inflammatory response, as evidenced by the absence of tissue necrosis and little fibrosis.
Immediate mild hypersensitivity-like reactions were uncommonly observed after vaccination, resulting in transient clinical signs such as vomiting, diarrhea or depression, in field efficacy studies. These clinical signs normally resolve without treatment. Anaphylaxis may occur in very rare cases. In case of such reactions, appropriate treatment is recommended.

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. Do not use during pregnancy and lactation.

4.8 Interactions 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.

4.9 Amounts to be administered and administration route

Intramuscular use.
Administer one dose of 2 ml to pigs in the neck behind the ear.

Vaccination schedule:
One injection from 3 weeks of age.

Shake well before administration and intermittently during the process of vaccination.

The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions. The vaccine is to be administered aseptically. During storage, a slight black deposit may appear and the emulsion may separate into two distinct phases. Upon shaking, the black deposit disappears and the emulsion becomes homogenous again.

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

A transient increase in body temperature (on average 0.8 °C) was observed 4 hours after administration of a 2-fold overdose. This resolved spontaneously within 24 hours without treatment.
Local tissue reaction in the form of swelling (below 2 cm in diameter) at the injection site was commonly observed and resolved within 2 days.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, inactivated viral and inactivated bacterial vaccines for pigs.
ATCvet code: QI09AL08

The vaccine contains an inactivated recombinant chimeric porcine circovirus type 1 containing the porcine circovirus type 2 ORF2 protein. The vaccine also contains inactivated *Mycoplasma hyopneumoniae.* It is intended to stimulate active immunity against PCV2 and *Mycoplasma hyopneumoniae* in pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Squalane
Poloxamer 401
Polysorbate 80
Monobasic potassium phosphate anhydrous
Sodium chloride

Potassium chloride
Disodium phosphate anhydrous
Sodium phosphate dibasic heptahydrate
Disodium tetraborate decahydrate
EDTA tetrasodium
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as package for sale: 24 months.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
A slight black deposit may appear and the emulsion may separate into two distinct phases during storage. Upon shaking, the black deposit disappears and the emulsion becomes homogenous again.

6.5 Nature and composition of immediate packaging

High density polyethylene vials of 50 ml, of 100 ml and of 250 ml (25, 50 and 125 doses), with a chlorobutyl elastomer closure and sealed with an aluminium cap.

Pack size:
Cardboard box of 1 vial of 50 ml (25 doses), 100ml (50 doses) or 250 ml (125 doses).
Cardboard box of 10 vials of 50 ml (25 doses) or 100 ml (50 doses).
Cardboard box of 4 vials of 250 ml (125 doses).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material 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 the local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBERS

Vm 42058/5072

9. DATE OF FIRST AUTHORISATION

06 November 2015

10. DATE OF REVISION OF THE TEXT

November 2021

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Approved 05 November 2021