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 2 ml dose 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*

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

Adjuvant:	
MetaStim containing:	
Squalane	0.4% (v/v)
Poloxamer 401	0.2% (v/v)
Polysorbate 80	0.032% (v/v)
Excipients:	
Thiomersal	0.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White homogenous emulsion.
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.

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.
Duration of immunity: 23 weeks.

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
Not applicable.

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.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Pigs (for fattening):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site inflammation[2], Injection site pain[3], injection site reddening[3], injection site swelling[3]
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reactions (e.g. depression, diarrhoea or vomiting)[4]
Very rare (1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[5]

[1] Transient; observed during the first 24 hours after vaccination. On average 1° C but may exceed 2° C in individual pigs This resolves spontaneously within 48 hours without treatment.

[2] 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 lymphocytic-granulomatous inflammatory response.

[3]The area of local tissue reaction is in general below 2 cm in diameter and may last to up 2 days.

[4] Normally resolve without treatment.

[5]In case of such reactions, appropriate treatment is recommended.

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.

4.7 Use during pregnancy, lactation or lay

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

Pregnancy and lactation:

Do not use during pregnancy and lactation.

Fertility:
No information is available on the safety of this vaccine in breeding boars. Do not use in breeding boars.

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.

4.9 Amount(s) 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
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: 2 years.
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.

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.

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 materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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 NUMBER

Vm 42058/5072

9. DATE OF FIRST AUTHORISATION

06 November 2015

10. DATE OF REVISION OF THE TEXT

June 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 22 June 2024