SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn CSF Marker lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:

Lyophilisate:
Live recombinant E2 gene-deleted bovine viral diarrhoea virus containing classical swine fever virus E2 gene (CP7_E2alf) $10^{4.8}$* to $10^{6.5}$ TCID**$_{50}$

* min 100 PD_{50} (protective dose 50%)
** Tissue culture infectious dose

Solvent:
Sodium chloride 9 mg/ml
Water for injections q.s.p. 1 ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate: Off-white.
Solvent: Clear colourless liquid.
After reconstitution, the suspension should be slightly pink clear liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

For active immunisation of pigs from 7 weeks of age onwards to prevent mortality and reduce infection and disease caused by classical swine fever virus (CSFV).

Onset of immunity: 14 days
Duration of immunity: 6 months

For active immunisation of breeding females to reduce transplacental infection caused by CSFV.

Onset of immunity: 21days
Duration of immunity has not been established.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Documentation provided for this vaccine supports that it is only to be used in an outbreak situation in herds within restricted control zones.

Protection against transplacental transmission of CSFV was shown 21 days after vaccination when challenge was applied in 6 pregnant sows with a moderately virulent CSFV strain. Partial protection against transplacental transmission of CSFV was observed when challenge was applied in 6 pregnant sows with a highly virulent CSFV strain.
Birth of persistently infected immunotolerant piglets represent a very high risk since they are shedding field virus and they cannot be identified serologically due to their seronegative status. Vaccination of breeding animals may be included in risk-based control strategies in case of outbreak and considering the above information.

The vaccine has shown reduced protection in studies of piglets with maternally derived antibodies compared to studies of piglets without maternally derived antibodies.

Studies in vaccinated breeding boars addressing potential shedding of virulent challenge virus in semen have not been conducted. Use of the vaccine in experimental studies in breeding boars has not revealed safety concerns. Therefore, the decision to vaccinate breeding boars and piglets with maternally derived antibodies should be taken based on the actual outbreak case and associated control zones.

RT-PCR tools could be used in outbreak situations to differentiate between the vaccine virus genome and those of field strains based on sequences unique to the CP7_E2alf.

4.5 Special precautions for use

Special precautions for use in animals

Vaccine virus genome is rarely detectable by RT-PCR in tonsils and lymph nodes for up to 63 days after vaccination and vaccine virus is very rarely detectable by virus isolation in tonsil for the first week after vaccination. Transplacental transmission of the vaccine virus has not been detected in the limited studies performed but cannot be excluded.

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:

Very Common (>1 animal / 10 animals treated):	Injection site swelling[1]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature[2]

[1] Transient, up to 5 mm in diameter and lasting for 1 day.
[2] Transient, up to 2.9°C within 4 hours after vaccination and spontaneously resolving within 1 day.

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 its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy.
See section 4.4.

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.

Reconstitute the lyophilisate aseptically with the solvent to obtain a suspension for injection.

After reconstitution, the suspension should be slightly pink clear liquid.

Basic vaccination
A single 1 ml dose should be administered intramuscularly to pigs from 7 weeks of age and breeding females.

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

None known.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccines, live recombinant E2 gene-deleted bovine viral diarrhoea virus containing classical swine fever virus E2 gene.

ATCvet Code: QI09AD04

To stimulate active immunity to classical swine fever virus.

The vaccine is a live recombinant E2 gene-deleted bovine viral diarrhoea virus containing classical swine fever virus E2 gene. The virus is grown in porcine cells.

Challenge studies were conducted with the highly virulent reference strain CSFV Koslov (genotype 1) and the moderately virulent, Roesrath strain (genotype 2, Germany 2009). Limited studies in young pigs support protection against CSF1045 (genotype 2, Germany 2009) and CSF1047 (genotype 2, Israel 2009) field strains.

The recombinant vaccine virus has potential marker properties for use in DIVA (differentiation between field virus infected and solely vaccinated animals). Diagnostic tools targeted to detection of antibody responses could enable DIVA strategies. Serological DIVA tools based on detection of CSFV antibodies other than those raised against E2, such as Erns antibody detection should be able to differentiate between antibody responses against Erns-BVDV after solely herd vaccination with CP7_E2alf from responses against Erns-CSFV after natural field CSFV infection.

DIVA efficiency depends on the performance of tests related to fitness for purpose in outbreak situations. Serological DIVA concept has been shown in principle, while actual DIVA tools remain to be tested on large panels of samples from emergency vaccination in outbreak situations.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
L2 Freeze-drying stabilizer composed as follows
Dextran 40

Casein hydrolysate
Lactose monohydrate
Sorbitol 70% (solution)
Sodium hydroxide
Water for injections
Dulbecco's Modified Eagle culture medium (DMEM)

Solvent:
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 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

Type I hydrolytic glass vials containing 10 or 50 doses of lyophilisate and 10 or 50 ml of solvent.

Lyophilisate: bromobutyl rubber stoppers and aluminium caps
Solvent: chlorobutyl rubber stoppers and aluminium caps

Cardboard box containing 1 vial with 10 doses of lyophilisate and 1 vial with 10 ml solvent.
Cardboard box containing 1 vial with 50 doses of lyophilisate and 1 vial with 50 ml solvent.

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 products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5074

9. DATE OF FIRST AUTHORISATION

10 February 2015

10. DATE OF REVISION OF THE TEXT

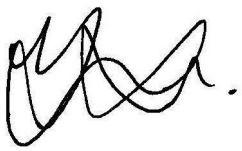
December 2023

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.



Approved: 19 March 2024