PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard box of 1 vial of 10 or 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn CSF Marker lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of 1 ml contains:

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

3. PACKAGE SIZE

10 doses
50 doses

4. TARGET SPECIES

Pigs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5074

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS Lyophilisate vial (10 and 50 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn CSF Marker

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Live recombinant CP7_E2alf: $10^{4.8}$ - $10^{6.5}$ $TCID_{50}$

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

5. ROUTE(S) OF ADMINISTRATION

IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS Solvent vial (10 and 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Suvaxyn CSF Marker

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Sodium chloride 9 mg/ml solution for injection.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use immediately.

5. ROUTE(S) OF ADMINISTRATION

IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Active substance:

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

Lyophilisate: Off-white.
Solvent: Clear colourless liquid.

3. TARGET SPECIES

Pigs.

4. INDICATIONS FOR USE

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: 21 days
Duration of immunity has not been established.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:

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 pregnant sows with a moderately virulent CSFV strain. Partial protection against transplacental transmission of CSFV was observed when challenge was applied in 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.

Special precautions for safe use in the target species:
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.

Pregnancy:
Can be used during pregnancy.

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.

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

Special restrictions for use and special conditions for use:
Council Directive 2001/89/EC and Commission Decision 2002/106 prohibit prophylactic vaccination within the European Union. Specific derogation is required to use this vaccine in an outbreak situation.

Any person intending to manufacture, import, possess, distribute, 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.

DIVA tests:
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 after solely herd vaccination with CP7_E2alf from responses 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.

7. ADVERSE EVENTS

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intramuscular use.

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

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute the lyophilisate aseptically with the solvent to obtain a suspension for injection. After reconstitution, the suspension should be slightly pink clear liquid.

10. WITHDRAWAL PERIODS

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp.. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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

Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5074

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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

December 2023

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

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

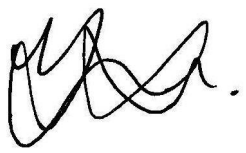
Manufacturer responsible for batch release:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
BELGIUM

17. OTHER INFORMATION

POM-V Veterinary medicinal product subject to prescription

For animal treatment only.



Approved: 19 March 2024