[Version 8.2,01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvac Ery Parvo emulsion for injection for pigs (AT, BE, BG, CZ, DE, EL, ES, FR, HR, HU, IE, IT, NL, PL, PT, RO, SK, UK(NI))
Porcivac Ery Parvo (DK, FI, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance:

Inactivated *Erysipelothrix rhusiopathiae*, serotype 2, strain SE-9	7.4 – 61.0 ELISA Units*
Inactivated Porcine parvovirus, strain PVP-7	320 – 5120 HIT**

* Serological response in vaccinated mice determined by ELISA according to Ph. Eur. 0064
** Titre of antibodies determined in vaccinated guinea-pigs by haemagglutination inhibition test according to Ph. Eur. 0965

Adjuvant:

Montanide ISA 201 VG	0.91 g

Excipient:

Thiomersal	0.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White homogeneous emulsion in which phase separation is not observed. Greyish sediment may form which can be dispersed by shaking.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

For the active immunisation of gilts, sows and boars to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 2, as shown under experimental challenge conditions in seronegative pigs.

For the active immunisation of gilts and sows for the reduction of transplacental infection in progeny caused by porcine parvovirus.

Onset of immunity:
E. rhusiopathiae: 3 weeks after completion of the primary vaccination scheme.
Porcine parvovirus: from the beginning of the gestation period after completion of the primary vaccination scheme.

Duration of immunity:
E. rhusiopathiae: 5 months

Porcine parvovirus: for the duration of gestation.

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

No information is available on the use of the vaccine in animals with maternally derived antibodies against porcine parvovirus.

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

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

People with known hypersensitivity to thiomersal should avoid contact with the product.

4.6 Adverse reactions (frequency and seriousness)

Very common adverse reactions:

Local redness can appear within 24 hours after the vaccination, which typically resolves without any treatment in less than 10 days but occasionally may persist up to 36 days.

Local increased temperature at the injection site can appear on the day of administration, which spontaneously resolves within 24 hours, although occasionally may persist up to 31 days.

Local pain at the injection site can appear on the day of administration, which typically resolves without any treatment before 4 days. Occasionally may persist up to 12 days.

Mild to moderate swelling (occasionally ≥ 5.1cm) and nodules (≥ 5.1 cm) can appear on the day of vaccination at the injection site, which typically resolve without any treatment in less than 17 days but occasionally may persist up to 33 days (swelling) or 69 days (nodules).

A transient increase in body temperature (average 0.85 °C, maximum 2.45 °C) can appear within 6 hours after vaccination, which spontaneously resolves within 24 hours without any known consequence to the health or productivity of the animal.

These reactions were observed under experimental and field conditions.

Common adverse reactions:

Transient apathy can appear within 6 hours after vaccination, which resolves without treatment within 24 hours. This was observed under experimental and field conditions.

General swelling in the neck can appear within two days after vaccination, which resolves without treatment within 5 days. This was observed under experimental and field conditions.

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

Can be used during pregnancy and lactation.

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 Amounts to be administered and administration route

Intramuscular use.

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

Use sterile syringes and needles.

Administer one dose of 2 ml intramuscularly in the neck muscles to pigs from 5 months of age according to the following scheme:

Primary vaccination scheme: two intramuscular injections of one dose, 4 weeks apart. In gilts and sows the second injection should be administered 2-3 weeks before mating or insemination.
Revaccination scheme for gilts and sows: one intramuscular injection of one dose 2-3 weeks before subsequent mating or insemination and not later than 5 months after previous vaccination.
Revaccination scheme for boars: one intramuscular injection every 5 months.

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

No information is available on the administration of an overdose of this vaccine.

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: QI09AL01 – porcine parvovirus and erysipelothrix

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide ISA 201 VG
Thiomersal
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate
Sodium chloride
Silicone antifoaming agent
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 packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Polypropylene colourless vial containing 50 ml (25 doses) or 100 ml (50 doses), with a type I bromobutyl rubber stopper, sealed with an aluminium closure.

Package sizes:
Cardboard box with 1 vial containing 50 ml (25 doses).
Cardboard box with 1 vial containing 100 ml (50 doses).

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

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS SYVA, S.A.

C/ Marqués de la Ensenada, 16
28004 MADRID
SPAIN

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 vial of 50 ml
Box of 1 vial of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvac Ery Parvo emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Active substance:

Inactivated *Erysipelothrix rhusiopathiae*, serotype 2, strain SE-9	7.4 – 61.0 ELISA Units
Inactivated Porcine parvovirus, strain PVP-7	320 – 5120 HIT

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

50 ml (25 doses)
100 ml (50 doses)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Shake well before use and intermittently during the process of vaccination.
Use sterile syringes and needles.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.
Store in the original package.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS SYVA, S.A.
C/ Marqués de la Ensenada, 16
28004 MADRID
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 50 ml
Vial of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvac Ery Parvo emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Active substance:

Inactivated *Erysipelothrix rhusiopathiae*, serotype 2, strain SE-9	7.4 – 61.0 ELISA Units
Inactivated Porcine parvovirus, strain PVP-7	320 – 5120 HIT

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

50 ml (25 doses)
100 ml (50 doses)

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Shake well before use and intermittently during the process of vaccination.
Use sterile syringes and needles.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.
Store in the original package.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS SYVA, S.A.
28004 MADRID
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Syvac Ery Parvo emulsion for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

LABORATORIOS SYVA, S.A.
C/ Marqués de la Ensenada, 16
28004 MADRID
SPAIN

Manufacturer responsible for batch release:

LABORATORIOS SYVA, S.A.
Parque Tecnológico de León
C/ Nicostrato Vela M15-M16
24009 LEÓN
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvac Ery Parvo emulsion for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 2 ml dose contains:

Active substance:

Inactivated *Erysipelothrix rhusiopathiae*, serotype 2, strain SE-9	7.4 – 61.0 ELISA Units*
Inactivated Porcine parvovirus, strain PVP-7	320 – 5120 HIT**

* Serological response in vaccinated mice determined by ELISA according to Ph. Eur. 0064
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Adjuvant:

Montanide ISA 201 VG	0.91 g

Excipient:

Thiomersal	0.2 mg

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4. INDICATION(S)

For the active immunisation of gilts, sows and boars to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 2, as shown under experimental challenge conditions in seronegative pigs.

For the active immunisation of gilts and sows for the reduction of transplacental infection in progeny caused by porcine parvovirus.

Onset of immunity:
E. rhusiopathiae: 3 weeks after completion of the primary vaccination scheme.
Porcine parvovirus: from the beginning of the gestation period after completion of the primary vaccination scheme.

Duration of immunity:
E. rhusiopathiae: 5 months
Porcine parvovirus: for the duration of gestation.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Very common adverse reactions:

Local redness can appear within 24 hours after the vaccination, which typically resolves without any treatment in less than 10 days but occasionally may persist up to 36 days.

Local increased temperature at the injection site can appear on the day of administration, which spontaneously resolves within 24 hours, although occasionally may persist up to 31 days.

Local pain at the injection site can appear on the day of administration, which typically resolves without any treatment before 4 days. Occasionally may persist up to 12 days.

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These reactions were observed under experimental and field conditions.

Common adverse reactions:

Transient apathy can appear within 6 hours after vaccination, which resolves without treatment within 24 hours. This was observed under experimental and field conditions.

General swelling in the neck can appear within two days after vaccination, which resolves without treatment within 5 days. This was observed under experimental and field conditions.

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- 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).

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 inform your veterinary surgeon.

Alternatively, you can report via your national reporting system (national system detail).

7. TARGET SPECIES

Pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.

Administer one dose of 2 ml intramuscularly in the neck muscles to pigs from 5 months of age according to the following scheme:

Primary vaccination scheme: two intramuscular injections of one dose, 4 weeks apart. In gilts and sows the second injection should be administered 2-3 weeks before mating or insemination.
Revaccination scheme for gilts and sows: one intramuscular injection of one dose 2-3 weeks before subsequent mating or insemination and not later than 5 months after previous vaccination.
Revaccination scheme for boars: one intramuscular injection every 5 months.

9. ADVICE ON CORRECT ADMINISTRATION

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

Use sterile syringes and needles.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Protect from light.
Store in the original package.

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

Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

No information is available on the use of the vaccine in animals with maternally derived antibodies against porcine parvovirus.

Special precautions for use in animals:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

People with known hypersensitivity to thiomersal should avoid contact with the product.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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.

Overdose (symptoms, emergency procedures, antidotes):

No information is available on the administration of an overdose of this vaccine.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size:
Cardboard box with 1 vial containing 50 ml (25 doses).
Cardboard box with 1 vial containing 100 ml (50 doses).

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.