

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvac Ery Parvo emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:

Erysipelothrix rhusiopathiae, serotype 2, strain SE-9, inactivated 7.4 – 61.0 ELISA Units*
Porcine parvovirus, strain PVP-7, inactivated 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

Adjuvants:

Montanide ISA 201 VG

0.91 g

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Thiomersal	0.2 mg
Potassium chloride	
Potassium dihydrogen phosphate	
Disodium phosphate	
Sodium chloride	
Silicon antifoaming agent	
Water for injections	

White or pinkish-white homogeneous emulsion in which phase separation is not observed. Greyish sediment may form which can be dispersed by shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

People with known hypersensitivity to thiomersal should avoid contact with this veterinary medicinal product.

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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable

3.6 Adverse events

Pigs

Very common (>1 animal / 10 animals treated):	Injection site reddening ¹ , Injection site warmth ² , Injection site pain ³ , Injection site swelling ⁴ , Injection site nodule ⁵ Hyperthermia ⁶
Common (1 to 10 animals / 100 animals treated):	Apathy ⁷ Local swelling (neck) ⁸

1. For up to 10 days, occasionally up to 36 days.
2. For up to 24 hours, occasionally up to 31 days.
3. For up to 4 days, occasionally up to 12 days.
4. For up to 17 days, occasionally up to 33 days, and of over 5.1 cm in diameter.
5. For up to 17 days, occasionally up to 69 days, and of over 5.1 cm in diameter.
6. For up to 1 day, maximum increase of 2.45 °C.
7. For up to 1 day.
8. For up to 5 days.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

QI09AL01

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

Store in the original package.

5.4 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).

Not all the pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS SYVA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10495/011/001

8. DATE OF FIRST AUTHORISATION

07/10/2022

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/03/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).