**B. PACKAGE LEAFLET**

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Syvac Ery Parvo emulsion for injection for pigs

## 2. 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:**

| | |
|---|---|
| Thiomersal | 0.2 mg |

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

## 3. Target species

Pigs.

## 4. Indications for use

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. Special warnings

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.

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.

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:

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

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

## 7. Adverse events

Pigs.

| Very common<br>(>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] (elevated body temperature) |
| Common<br>(1 to 10 animals / 100 animals treated): |
| Apathy (lack of energy)[7]<br>Local swelling (neck)[8] |

1. For up to10 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 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 its local representative 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.

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 periods

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 precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

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

Not all pack sizes may be marketed.

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

## 15. Date on which the package leaflet was last revised

{MM/YYYY}
{DD/MM/YYYY}
{DD month YYYY}

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

## 16. Contact details

Marketing authorisation holder:
Laboratorios Syva S.A.
Calle Marqués de la Ensenada, 16
28004 MADRID
SPAIN

Manufacturer responsible for batch release:
Laboratorios Syva S.A.

Parque Tecnológico de León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN

Local representative and contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico de León
Calle Nicostrato Vela M15-M16
ES-24009 León
Tel: +34 987 800 800
E-mail: farmacovigilancia@syva.es