[Version 8.2,01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac Ery emulsion for injection for pigs (AT, BE, BG, CY, CZ, DE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK(NI))
Ingelvac Ery vet (NO)
Ingelvac Ery (EE)
Syvagen Ery (DK)

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

Adjuvants:
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.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

For the active immunisation of pigs 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.

Onset of immunity: 3 weeks after completion of the primary vaccination scheme.
Duration of immunity: 5 months

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only

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 43 days.

Local 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 33 days.

Mild to moderate swelling (occasionally ≥ 5.1cm) and nodules (≤ 5 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 38 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 resolved without treatment within 24 hours. This was observed under experimental and field conditions.

Hypersensitivity-like reactions, causing affected breathing and muscular stiffness, which resolved without treatment in a few minutes, was observed in one field study.

Uncommon adverse reactions:

General swelling in the neck can appear within two days after vaccination, which resolved without treatment within 13 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, in accordance with the recommendations in SPC Section 4.9

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.

Administer one dose of 2 ml intramuscularly in the neck muscles to pigs from 12 weeks of age according to the following scheme:

Primary vaccination scheme: two intramuscular injections of one dose, 4 weeks apart.
Revaccination scheme: one intramuscular injection of one dose at least every 5 months.
Can be used for vaccination of pregnant animals, however if vaccinating according to the primary vaccination scheme, administer the first dose prior to mating or insemination.

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: Inactivated bacterial vaccines for pigs, erysipelothrix.
ATCvet code: QI09AB03.

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 100 ml, with a type I bromobutyl rubber stopper, sealed with an aluminium closure.

Package sizes:

Cardboard box with 1 vial containing 100 ml.

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.U.
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SPAIN

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

[For DCP: To be completed in accordance with national requirements after conclusion of the DC phase]