LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 vial of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac Ery 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

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

100 ml

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.
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.
Keep the vial in the outer carton.

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.

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

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/4000

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac Ery 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

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml

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.
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.
Keep the vial in the outer carton.

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

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/4000

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Ingelvac Ery 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:

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturer responsible for batch release:

LABORATORIOS SYVA, S.A.U.
Parque Tecnológico de León
Av. Portugal s/n
Parcelas M15-M16
24009 LEÓN
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac Ery 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*
* 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

White homogeneous emulsion in which phase separation is not observed.

4. INDICATION(S)

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.

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 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).

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 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

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.
Keep the vial in the outer carton.

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.

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, in accordance with the recommendations in Dosage Section.

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 in 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

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

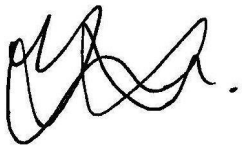
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2022

15. OTHER INFORMATION

Pack size:
Cardboard box with 1 vial containing 100 ml.

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



Approved: 15 June 2022