

[Version 8.2,01/2021]

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 vial of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvac 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

LABORATORIOS SYVA, S.A.U.

Av. Párroco Pablo Diez, 49-57

24010 LEÓN

SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

[Item to be completed by the marketing authorisation holder once the marketing authorisation has been granted.]

[For MRP/DCP only: Number allocated by the Member State. To be completed in accordance with national requirements after conclusion of the MR phase.]

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

Syvac 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

LABORATORIOS SYVA, S.A.U.
24010 LEÓN
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}