

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

cardboard box / 1 × 10 ml, 1 × 50 ml, 1 × 100 ml, 1 × 250 ml

label for plastic box / 10 × 10 ml

label for glass vial / 100 ml

label for plastic vial / 120 ml (filled volume 100 ml), 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIOSUIS ParvoEry suspension for injection for pigs

(CZ, EE, EL, HR, HU, IE, LT, LV, PL, BG, DE, UK(NI))

PORVAXIN Parvo+Ery suspension for injection for pigs

(ES, PT)

Parvovac Ery suspension for injection for pigs

(DK, SE, NO)

FIXR ParvoEry suspension for injection for pigs

(NL, BE)

2. STATEMENT OF ACTIVE SUBSTANCES

Composition 2 ml (1 dose):

Porcine parvovirus, inactivated, strain CAPM V198, S-27

≥ 4 log₂ *)

Erysipelothrix rhusiopathiae inactivated, serotype 2, strain 2-64

RP ≥ 1 **)

*), **) see package leaflet

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

1 × 10 ml (5 doses), 1 × 50 ml (25 doses), 1 × 100 ml (50 doses), 1 × 250 ml (125 doses)

10 × 10 ml (10 × 5 doses)

100 ml (50 doses)

250 ml (125 doses)

5. TARGET SPECIES

Pigs (gilts, sows)



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

Protect from frost.

Protect from light.

12. SPECIAL 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

Bioveta, a. s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

16. MARKETING AUTHORISATION NUMBER(S)

Marketing authorisation number:

17. MANUFACTURER’S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

label for glass vial / 10 ml, 50 ml

label for plastic vial / 60 ml (filled volume 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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(CZ, EE, EL, HR, HU, IE, LT, LV, PL, BG, DE, UK(NI))

PORVAXIN Parvo+Ery suspension for injection for pigs
(ES, PT)

Parvovac Ery suspension for injection for pigs
(DK, SE, NO)

FIXR ParvoEry suspension for injection for pigs
(NL, BE)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Composition 2 ml (1 dose):

Porcine parvovirus, inactivated, strain CAPM V198, S-27 $\geq 4 \log_2$

Erysipelothrix rhusiopathiae inactivated, serotype 2, strain 2-64 $RP \geq 1$

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml (5 doses), 50 ml (25 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

Once opened use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.