SPC

Prime Pac® PRRS

SUMMARY OF PRODUCT CHARACTERISTICS

Registration file / May 2020

MSD Animal Health

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prime Pac PRRS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Modified live PRRS virus type 2 strain Nebraska-attenuated:
at least 4.0 $\log_{10}$ $TCID_{50}$ * per dose

*tissue culture infective dose 50%

3. PHARMACEUTICAL FORM

Light yellow to white lyophilisate and clear to white solvent for suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species
Pig

4.2 Indications for use
For active immunisation of clinically healthy pigs in a porcine reproductive and respiratory syndrome (PRRS) virus contaminated environment to reduce viraemia and clinical signs caused by infection with PRRS virus.

Onset of immunity has been demonstrated at 4 weeks post vaccination.
Duration of immunity has been demonstrated to last for at least 23 weeks.

4.3 Contraindications
Do not use in herds where the prevalence of PRRS has not been established by appropriate diagnostic methods.

4.4 Special warnings
The safety of the vaccine for the reproductive performance in boars has not been established.

4.5 Special precautions for use

Special precautions for use in animals
The vaccine virus may spread to PRRS virus naïve in contact pigs during 5 weeks after vaccination. For PRRS virus in general, the most common spreading route is via direct contact, but spreading via contaminated objects or via the air cannot be excluded. PRRS virus may be excreted in semen for many weeks therefore the use in boars producing semen for PRRS seronegative herds is not recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)
Local reactions (up to 1.5 cm in diameter) may be observed the first day after intramuscular vaccination and up to 14 days after intradermal administration. A transient hyperthermia may occur. In rare cases vaccination may evoke hypersensitivity reactions such as dyspnoea, hyperaemia, recumbence, tremor, excitation and vomiting. In such cases symptomatic treatment is recommended. These signs normally disappear spontaneously and totally within a short period after vaccination.

4.7 Use during pregnancy and lactation
PRRS virus-naïve gilts and sows should not be vaccinated during pregnancy, as this can have negative effects. Vaccination during pregnancy is safe when it is performed in gilts and sows which are already immunized against PRRS virus via vaccination or field infection. The vaccine can be used during lactation.

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
Rehydrate freeze dried vial with the accompanying solvent and mix well.
The vaccine is administered by intramuscular injection of 1 ml or intradermal administration of 0.2 ml to healthy pigs of 2 weeks of age or older.

Finishing pigs: a single vaccination is sufficient for protection until slaughter.
Breeding pigs: For gilts and sows a vaccination 2-4 weeks before mating is recommended. To maintain a high and homologous level of immunity, revaccination at regular intervals is recommended, either before each next gestation or at random at 4 month intervals. Pregnant sows should only be vaccinated after previous exposure to PRRS virus.

It is advised to vaccinate all target pigs within a herd from the earliest recommended age onwards.
Newly introduced PRRS virus-naïve animals (e.g. replacement gilts from PRRS virusnegative herds) should be vaccinated prior to pregnancy.

Use sterile syringes and needles.

4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary)
Not different from single dose (see 4.6)

4.11 Withdrawal period(s)
Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against PRRS virus, ATCvet code: QI09AD03

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities
Do not mix with any other veterinary medicinal product, except the solvent supplied with the product.

6.2 Shelf life
Shelf life of the lyophilisate as packed for sale: 2 years
Shelf life after reconstitution according to directions: use immediately.

6.3 Special precautions for storage
Store in a refrigerator (2 °C - 8 °C).

6.4 Nature and composition of immediate packaging

Lyophilisate:
Glass vial closed with a rubber stopper and aluminium cap.

Solvent:
Glass orPET vial closed with a rubber stopper and aluminium cap.

IM presentation:
Solvent may be packed together with the lyophilisate or separately:
Cardboard boxes with 1 or 10 glass vials with 10, 20, 50, 100 or 200 doses of freeze-dried vaccine.
Cardboard boxes with 1 or 10 glass or PET vials with 10, 20, 50, 100 or 200 ml of solvent.

Cardboard boxes with 1 or 10 glass vials with 10, 20, 50, 100 or 200 doses of freeze-dried vaccine plus 1 or 10 glass or PET vials with 10, 20, 50, 100 or 200 ml of solvent.

ID presentation:
Cardboard boxes with 1, 5 or 10 glass vials with 25, 50, or 100 doses of freeze-dried vaccine plus 1, 5 or 10 glass or PET vials with 5, 10, or 20 ml of solvent.

Not all pack sizes may be marketed.

6.5 Special precautions for the disposal of unused medicinal product or waste materials derived from the use of such products
Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

ANNEX I

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR ON THE IMMEDIATEPACKAGE (for intramuscular use)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prime Pac PRRS

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Modified live PRRS virus type 2, strain Nebraska-attenuated: at least 4.0 $\log_{10}$ $TCID_{50}$ per dose

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

10 doses
20 doses
50 doses
100 doses
200 doses
10x10 doses
10x20 doses
10x50 doses
10x100 doses
10x200 doses

5.METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular application
See package leaflet for details.

6.EXPIRY DATE

EXP: [(month/year)...../.....]

7.SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8 °C).

PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR ON THE IMMEDIATEPACKAGE (for intramuscular use)

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

9. THE WORDS "KEEP OUT OF REACH AND SIGHT OF CHILDREN"

Keep out of reach and sight of children

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LOT: .....

PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR ON THE IMMEDIATEPACKAGE (for intradermal use)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prime Pac PRRS

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Modified live PRRS virus type 2, strain Nebraska-attenuated: at least 4.0 $\log_{10}$ $TCID_{50}$ per dose

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

25 doses
50 doses
100 doses
5x25 doses
5x50 doses
5x100 doses
10x25 doses
10x50 doses
10x100 doses

5.METHOD AND ROUTE(S) OF ADMINISTRATION

Intradermal application
See package leaflet for details.

6.EXPIRY DATE

EXP: [(month/year)...../.....]

7.SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8 °C).

PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR ON THE IMMEDIATEPACKAGE (for intradermal use)

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

9. THE WORDS "KEEP OUT OF REACH AND SIGHT OF CHILDREN"

Keep out of reach and sight of children

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V.
Boxmeer - The Netherlands

9. THE WORDS "KEEP OUT OF REACH AND SIGHT OF CHILDREN"

LOT: .....

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (Vial with lyophilisate)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prime Pac PRRS

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

PRRSV type 2, strain Nebr.-att.: at least 4.0 $\log_{10}$ $TCID_{50}$ per dose

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

10 doses
20 doses
25 doses
50 doses
100 doses
200 doses

4. ROUTES OF ADMINISTRATION

IM or ID

5. BATCH NUMBER

LOT: ……

6. EXPIRY DATE

EXP: [(month/year)…../…….]

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prime Pac PRRS

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)

Modified live PRRS virus type 2, strain Nebraska-attenuated: at least 4.0 $\log_{10}$ $TCID_{50}$* per dose
*tissue culture infective dose 50%

3. PRODUCT OF INTERVET INTERNATIONAL BV BOXMEER - THE NETHERLANDS

4. INDICATION(S)

For active immunisation of clinically healthy pigs in a porcine reproductive and respiratory syndrome (PRRS) virus type 2 contaminated environment to reduce viraemia and clinical signs caused by infection with PRRS virus.

5. CONTRA-INDICATIONS

Do not use in herds where the prevalence of PRRS has not been established by appropriate diagnostic methods.

6. ADVERSE REACTIONS

Local reactions (up to 1.5 cm in diameter) may be observed the first day after intramuscular vaccination and up to 14 days after intradermal administration. A transient hyperthermia may occur. In rare cases vaccination may evoke hypersensitivity reactions such as dyspnoea, hyperaemia, recumbence, tremor, excitation and vomiting. In such cases symptomatic treatment is recommended. These signs normally disappear spontaneously and totally within a short period after vaccination.

7. TARGET SPECIES

Pig

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The vaccine is administered by intramuscular injection of 1 ml or intradermal administration of 0.2 ml to healthy pigs of 2 weeks of age or older.

9. ADVICE ON CORRECT ADMINISTRATION

Rehydrate freeze dried vial with the accompanying solvent, mix well and use immediately.

Finishing pigs: a single vaccination is sufficient for protection until slaughter.
Breeding pigs: For gilts a (re)vaccination 2-4 weeks before mating is recommended.
To maintain a high and homologous level of immunity,
revaccination at regular intervals is recommended, either before each next gestation or at random at 4 month intervals. Pregnant sows should only be vaccinated after previous exposure to PRRS virus.

It is advised to vaccinate all target pigs within a herd from the earliest recommended age onwards.

Newly introduced PRRS virus-naïve animals (e.g. replacement gilts from PRRS virusnegative herds) should be vaccinated prior to pregnancy.
Use sterile syringes and needles.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2°C - 8 °C).

12. SPECIAL WARNINGS, IF NECESSARY

The vaccine virus may spread to PRRS virus naïve in contact pigs during 5 weeks after vaccination. For PRRS virus in general, the most common spreading route is via direct contact, but spreading via contaminated objects or via the air cannot be excluded. PRRS virus may be excreted in semen for many weeks therefore the use in boars producing semen for PRRS seronegative herds is not recommended. The vaccine can be used during lactation.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Do not mix with any other veterinary medicinal product, except the solvent supplied with the product. 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.

13. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Date: .....

14. WITHDRAWAL PERIOD

For animal treatment only.