ANNEX II

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substance

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

Burgwedel Biotech GmbH
Im Langen Felde 5
30938 Burgwedel
GERMANY

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes {20, 50, 100, 200 and 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose of 2 ml contains:
Porcine circovirus type 2 ORF2 subunit antigen: ≥ 3720 Antigenic Units.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

20 ml
50 ml
100 ml
200 ml
500 ml
10 x 20 ml
10 x 50 ml
10 x 100 ml
10 x 200 ml
10 x 500 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous. Read the package leaflet before use.
Shake well before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C).
Do not freeze. Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

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

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5054

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials {100, 200 and 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose of 2 ml contains:
PCV2 ORF2 subunit antigen: ≥ 3720 Antigenic Units.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

100 ml
200 ml
500 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous. Read the package leaflet before use.
Shake well before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C).
Do not freeze. Protect from light.

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. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

15. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials {20 and 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV emulsion for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per 2 ml dose:
PCV2 ORF2 subunit antigen: ≥ 3720 Antigenic Units.

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

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IM
Shake well before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Porcilis PCV 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 and manufacturer responsible for batch release:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

Buckinghamshire

MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PCV emulsion for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each dose of 2 ml contains:
Porcine circovirus type 2 ORF2 subunit antigen: ≥ 3720 Antigenic Units as determined in the *in vitro* potency test (AlphaLISA)
Adjuvants:
25 mg dl-α-tocopheryl acetate
346 mg light liquid paraffin.

Emulsion for injection. Opalescent white, with brown resuspendable sediment.

4. INDICATION(S)

For the active immunisation of pigs to reduce the virus load in blood and lymphoid tissues and to reduce mortality and weight loss associated with PCV2 infection occurring during the fattening period.

Onset of immunity: 2 weeks
Duration of immunity: 22 weeks.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

In laboratory studies and field trials:

Transient local reactions at the injection site were very commonly observed after vaccination mainly in the form of a hard, warm and sometimes painful swelling (diameter up to 10 cm). These reactions resolve spontaneously over a period of approximately 14–21 days without any major consequence on the general health status of the animals. Immediate systemic hypersensitivity-like reactions were commonly observed after vaccination, resulting in minor neurological symptoms such as tremors and/or excitation, which normally resolve within minutes without requiring treatment. A transient increase in body temperature, normally not exceeding 1 °C, was very commonly observed until 2 days after vaccination. In individual animals, an increase of rectal temperature of 2.5 °C lasting less than 24 hours was uncommonly observed.
In some piglets depression and a reduced feed intake for up to 5 days were uncommonly observed. Vaccination may result in a transient impairment of growth rate in the immediate period after administration of the vaccine.

In post marketing experience:

In very rare cases anaphylactic-type reactions can occur, which may be life-threatening. In the event of such reactions, treatment may be needed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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, including isolated reports treated).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

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

Administer one dose (2 ml), by intramuscular injection in the neck in the area behind the ear, according to the following schedule:

In the case of low to medium levels of maternally derived antibodies against PCV2 a single vaccination (2 ml) to pigs from an age of 3 weeks onwards is advised.

When it is expected that higher levels of maternally derived antibodies against PCV2 are present, the following schedule of two vaccinations is advised: the first injection (2 ml) can be given from an age of 3–5 days, the second injection (2 ml) 2–3 weeks later.

High levels of MDA may be expected when sows/gilts are vaccinated against PCV2 virus or when sows/gilts have recently been exposed to high levels of PCV2 virus. In such cases it is advised to perform PCV2 serology, using suitable diagnostics, to select the most appropriate vaccination schedule. In case of doubt, apply the two shot vaccination schedule.

9. ADVICE ON CORRECT ADMINISTRATION

Before using the vaccine allow it to reach room temperature (15–25 °C) and shake well before use. Avoid multiple vial broaching.
Use sterile syringes and needles.
Avoid introduction of contamination.
Avoid use of vaccination equipment with rubber parts.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Do not freeze. Protect from light.
Shelf-life after first opening the container: 8 hours.
Do not use this veterinary medicinal product after the expiry date (EXP) which is stated on the carton and the vial.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Vaccinate only healthy animals.

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 product, seek prompt medical advice even if only a very small amount is injected and take the package insert 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.

Pregnancy and lactation:
Do not use during pregnancy and lactation.

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 decided on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):
Following the administration of a double dose of vaccine no side effects other than those described under “adverse reactions” have been observed.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

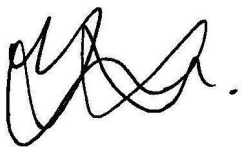
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

15. OTHER INFORMATION

Pack sizes: cardboard boxes with either 1 or 10 vials of 20, 50, 100, 200 or 500 ml (10, 25, 50, 100 or 250 doses).
Not all pack sizes may be marketed.



Approved: 10 September 2021