ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD Lyophilisate and suspension for suspension for injection for cattle

2. STATEMENT OF ACTIVESUBSTANCES

One dose (4ml) contains:
Lyophilised fraction
Modified live Bovine Pi3 virus strain RLB 103 $10^{5.0}$-$10^{8.6}$ $CCID_{50}$*
Modified live BRSV strain 375 $10^{5.0}$-$10^{7.2}$ $CCID_{50}$*

* $CCID_{50}$ = Cell Culture Infectious Dose 50%

Liquid fraction
Inactivated BVDV Type 1, strains 5960 (cytopathic) and 6309 (non-cytopathic) ≥ 3.0 log_2*

*To induce a GMT seroneutralisation titre in guinea pigs of at least 3.0 log_2

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection

4. PACKAGE SIZE

1x5 dose vial of lyophilized fraction
1x5 dose (20 ml) vial of liquid fraction
1x25 dose vial of lyophilized fraction
1x25 dose (100 ml) vial of liquid fraction

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf-life after reconstitution: 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Dispose of waste material in accordance with local requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4124

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – LYOPHILISED FRACTION (5 and 25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD Lyophilized fraction.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (4ml) contains:
Modified live Bovine Pi3 virus strain RLB 103 $10^{5.0}$-$10^{8.6}$ $CCID_{50}$*
Modified live BRSV strain 375 $10^{5.0}$-$10^{7.2}$ $CCID_{50}$*

* $CCID_{50}$ = Cell Culture Infectious Dose 50%

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

5 doses
25 doses

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

Withdrawal period(s): Zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP:
Shelf life after reconstitution: 2 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – LIQUID FRACTION (20 ml and 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD Liquid fraction

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (4 ml) contains:
Inactivated BVDV Type 1, strains 5960 (cytopathic) and 6309 (non-cytopathic) ≥ 3.0 log_2*
*To induce a GMT seroneutralisation titre in guinea pigs of at least 3.0 log_2

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

5 doses (20 ml)
25 doses (100 ml)

4. ROUTE(S) OF ADMINISTRATION

IM.

5. WITHDRAWAL PERIOD (S)

Withdrawal period(s): Zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP:
Shelf life after reconstitution: 2 hours

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Rispoval 3 BRSV Pi3 BVD
Lyophilisate and suspension for suspension for injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD
Lyophilisate and suspension for suspension for injection for cattle.

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

One dose (4 ml) contains:

Active substance(s):

Lyophilised fraction

Parainfluenza 3 virus, modified live strain RLB 103	$10^{5.0}$ to $10^{8.6}$ $CCID_{50}$
Bovine Respiratory Syncytial Virus, modified live strain 375	$10^{5.0}$ to $10^{7.2}$ $CCID_{50}$

Liquid fraction
Bovine Virus Diarrhoea Virus Type 1, inactivated strains 5960 (cytopathic) and 6309 (non-cytopathic), to induce a GMT seroneutralisation titre in guinea pigs of at least 3.0 log_2

Adjuvant

Alhydrogel 2%	0.8 ml (equivalent to 24.36 mg of aluminium hydroxide)

$CCID_{50}$ = Cell Culture Infectious Dose 50%

4. INDICATION(S)

For active immunisation of calves from 12 weeks of age to:

- reduce virus excretion and the clinical signs caused by bovine Pi3 virus;
- reduce virus excretion caused by BRSV infection and
- reduce virus excretion and the severity of the leucopenia induced by BVDV Type 1 infection.

Onset of immunity: 3 weeks after vaccination.

Duration of immunity: 6 months (demonstrated by challenge studies) after vaccination for BRSV and BVDV Type 1. Duration of immunity has not been established for bovine Pi3 virus.

Efficacy has not been demonstrated against BVDV Type 2 strains.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Transient and mild hyperthermia which can last for 2 days and a transient, minor local inflammation reaction of up to 0.5 cm which disappears within 15 days can occur very commonly after administration of the vaccine. Very rarely, the vaccine may cause hypersensitivity reactions. In a case of anaphylactic reaction, symptomatic treatment should be provided.

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 though those not already listed in this package leaflet or you think the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

Dose: 4 ml
Route: Intramuscular

Vaccination scheme:
Basic immunisation: Two doses, each of 4 ml, 3-4 weeks apart from 12 weeks of age.

Booster vaccinations: If protection against BRSV and BVDV Type 1 is required, then animals should be revaccinated after 6 months.

Animals should be preferably vaccinated at least 3 weeks before a period of stress or high infection risk like re-grouping or transport of animals, or the start of autumn season.

The duration of immunity of the Pi3 component is not known.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute the vaccine by adding the liquid to the vial containing the lyophilized fraction.

When the lyophilised fraction and liquid fraction are filled in equally sized vials, inject the entire liquid fraction into the lyophilized fraction vial.

When the lyophilised fraction is filled in a smaller vial size than the liquid fraction, the reconstitution of the vaccine is carried out in 2 steps:

1. Inject 10ml of the liquid fraction on the lyophilised plug in the lyophilized fraction vial.
2. Shake well and extract the reconstituted lyophilised fraction from the lyophilized fraction vial and mix with the liquid fraction in the liquid fraction vial.

Shake well before use.

10. WITHDRAWAL PERIOD (S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C - 8 °C). Protect from light. Do not freeze.

Do not use after the expiry date which is stated on the label.
Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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 label to the physician.

Pregnancy and lactation:
The safety and efficacy of the veterinary medicinal product has not been established during 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:
Reactions after administration of an overdose of vaccine are not different from those after the single dose.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent recommended for use with the veterinary medicinal product.

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

Any unused veterinary product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

The vaccine has a broad cross-neutralising ability against various current European strains of BVDV Type 1 as measured *in vitro* by virus neutralisation test. Cross neutralisation at a lower level has also been demonstrated to BVDV Type 2 strains.

Pack Size:
Cardboard box with 1 vial of lyophilized fraction (5 doses) and 1 vial of liquid fraction (20 ml).
Cardboard box with 1 vial of lyophilized fraction (25 doses) and 1 vial of liquid fraction (100 ml).

Not all pack sizes may be marketed.

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

For animal treatment only.
To be supplied only on veterinary prescription.

Approved 10 January 2020