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.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4 ml dose contains:

Lyophilisate:
Modified live Bovine Pi3 virus, strain RLB 103 $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$
Modified live BRSV, strain 375 $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$

Suspension:
Inactivated BVDV Type 1, strains 5960 (cytopathic) and 6309 (non-cytopathic) ≥ 3.0 log_2

3. PACKAGE SIZE

1 x 5 doses
1 x 25 doses

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

14. MARKETING AUTHORISATION NUMBERS

Vm 60021/3044

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – LYOPHILISATE (5 and 25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Bovine Pi3 virus, BRSV

5 doses
25 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL ON GLASS VIAL – SUSPENSION (20 ml and 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

BVDV Type 1

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each 4 ml dose contains:

Active substances:

Lyophilisate:

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

Suspension:

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

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

Adjuvant:

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

Lyophilisate: slightly coloured freeze-dried pellet.
Suspension: slightly coloured turbid liquid which might contain a loose sediment. On shaking well, the sediment is easily resuspended.

3. Target species

Cattle.

4. Indications for use

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.

Duration of immunity: 6 months (demonstrated by challenge studies) 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. Special warnings

Special warnings:
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 the 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 made on a case by case basis.

Overdose:
No adverse events other than those mentioned in section “Adverse events” were observed after administration of an overdose of the vaccine.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except suspension recommended for use with the veterinary medicinal product.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Hyperthermia[1] Injection site inflammation[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction, anaphylactic-type reaction[3]

[1]Transient and mild; can last for 2 days.
[2]Transient and minor; up to 0.5 cm which disappears within 15 days.

[3]In case of anaphylactic reaction (severe allergic reaction), symptomatic treatment should be provided.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Dose: 4 ml.

Route: intramuscular.

Vaccination scheme:

Administer one dose (4 ml) of the reconstituted vaccine according to the following 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

Reconstitution of the vaccine:

Reconstitute the vaccine by adding the suspension to the vial containing the lyophilisate.

When the lyophilisate and suspension are filled in equally sized vials, inject the entire suspension into the vial containing the lyophilisate.

When the lyophilisate is filled in a smaller vial size than the suspension, the reconstitution of the vaccine is carried out in 2 steps:

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

Shake well before use.

Reconstituted product is a slightly coloured turbid liquid which might contain a loose sediment which is easily resuspended on shaking well.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 2 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 60021/3044

Cardboard box with 1 vial of lyophilisate (5 doses) and 1 vial of suspension (20 ml).
Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of suspension (100 ml).

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

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

17. Other information

To stimulate an active immunity against Pi3, BRSV and BVDV Type 1.

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.

Gavin Hall
Approved: 14 January 2025