

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Rispoval 4 – Outer Carton**  
**1 x 25ml (5 doses)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Rispoval 4 lyophilisate and suspension for suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 5ml dose contains:

**Active substances:**

**Suspension:**

- |                                                 |                      |
|-------------------------------------------------|----------------------|
| - Infectious Bovine Rhinotracheitis (IBR) virus | min. GMT $2\log_2^*$ |
| - Bovine Viral Diarrhoea (BVD) virus            | min. GMT $5\log_2^*$ |

\* GMT Serological titre induced after injection to calves.

**Lyophilisate:**

- |                                             |                                    |
|---------------------------------------------|------------------------------------|
| - Bovine Parainfluenza 3 (PI3) virus        | min. $10^{5.0}$ CCID <sub>50</sub> |
| - Bovine Respiratory Syncytial Virus (BRSV) | min. $10^{5.0}$ CCID <sub>50</sub> |

**3. PACKAGE SIZE**

1 x 5 dose lyophilisate  
1 x 5 dose suspension (25 ml)

**4. TARGET SPECIES**

Cattle.

**5. INDICATIONS**

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**6. ROUTES OF ADMINISTRATION**

Intramuscular use.

**7. WITHDRAWAL PERIODS**

Zero days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted, use within 2 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated (2 °C – 8 °C).

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.

**14. MARKETING AUTHORISATION NUMBERS**

Vm 60021/3018

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Rispoval 4 – Lyophilisate vial label**  
**5 doses**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Rispoval 4

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Lyophilisate containing BRSV,  $\geq 10^{5.0}$  CCID<sub>50</sub>, and PI3 virus,  $\geq 10^{5.0}$  CCID<sub>50</sub>.  
Only to be mixed with the suspension fraction of Rispoval 4.

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp.  
Once reconstituted, use within 2 hours.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Rispoval 4 – Solvent vial label**  
**5 doses**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Rispoval 4

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Suspension containing IBR virus,  $\geq$  GMT  $2\log_2$ , and BVD virus,  $\geq$  GMT  $5\log_2$ .  
Only to be mixed with the lyophilisate fraction of Rispoval 4.

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

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

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Rispoval 4 - Lyophilisate and suspension for suspension for injection for cattle

### 2. Composition

Each 5 ml dose contains:

#### **Active substances:**

##### Suspension fraction:

Infectious Bovine Rhinotracheitis (IBR) virus, strain Cooper,  $\geq$  GMT 2 log<sub>2</sub> \*

Bovine Viral Diarrhoea (BVD) virus, cytopathic strain 5960,  
and Bovine Viral Diarrhoea (BVD) virus, non-cytopathic strain 6309,  $\geq$  GMT 5 log<sub>2</sub> \*

\* GMT Serological titre induced after injection to calves.

##### Lyophilisate fraction:

Bovine Parainfluenza 3 (PI3) virus, thermosensitive strain RLB103,  
minimum titre at the end of shelf life,  $>$  or equal 10<sup>5.0</sup> CCID<sub>50</sub>

Bovine Respiratory Syncytial Virus (BRSV) strain 375,  
minimum titre at the end of shelf life,  $>$  or equal 10<sup>5.0</sup> CCID<sub>50</sub>

#### **Adjuvant:**

Aluminium hydroxide (2 % Al<sub>2</sub>O<sub>3</sub>)  $\leq$  5.2 mg Al<sub>2</sub>O<sub>3</sub> per ml

##### Liquid fraction:

Slightly coloured turbid liquid, which might contain loose sediment. On shaking well, the sediment is easily resuspended.

##### Freeze-dried fraction:

Slightly coloured freeze-dried pellet.

### 3. Target species

Cattle.

### 4. Indications for use

For active immunisation of cattle to reduce infection, clinical signs and respiratory disease caused by Bovine Respiratory Syncytial virus (BRSV), Infectious Bovine Rhinotracheitis (IBR, commonly known as BHV-1) virus and Parainfluenza virus type 3 (PI3); and leukopenia and viraemia caused by the Bovine Viral Diarrhoea (BVD) virus Type I, cytopathic and non-cytopathic strains.

## 5. Contraindications

None.

## 6. Special warnings

Vaccinate healthy animals only.

Pregnancy:

Do not use during the whole pregnancy.

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Rispoval Pasteurella.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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.

Major incompatibilities:

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

## 7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection reaction <sup>1</sup>	site
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<sup>1</sup> Mild, transient. Up to 0,5cm and completely resolved within 15days.

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](mailto:adverse.events@vmd.gov.uk)

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

**DOSE:** 5 ml

**ROUTE:** Intramuscular use.

Reconstitute the vaccine by adding the liquid to the vial containing the powder component.

When the lyophilised fraction and liquid fraction are filled in equally sized vials:

- Inject the entire liquid fraction into the freeze-dried 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:

- Inject 10ml of the liquid fraction on the lyophilised plug in the freeze-dried vial.
- Shake well and extract the reconstituted lyophilised fraction from the freeze-dried vial and mix with the liquid fraction in the liquid fraction vial.

## **VACCINATION PROGRAMME:**

### **For cattle over 3 months of age:**

Two doses of 5ml of reconstituted vaccine should be given three to four weeks apart to cattle.

Ideally, calves should be vaccinated at least 2 weeks before transport, mixing of animals of different origins, housing, or any other event which may cause the animals to be stressed or exposed to new infections. Calves are usually most susceptible during early autumn. The vaccine will protect animals against BRSV, PI3, IBR and BVD for at least 6 months, which will cover the period of risk from respiratory infections.

Should cattle be at risk from these respiratory diseases at a subsequent time, the same vaccination scheme is recommended at least 14 days prior to the period of expected disease challenge.

### **For cattle over 3 weeks of age:**

For cattle from 3 weeks of age, vaccination leads to seroconversion of seronegative calves vaccinated at 3 and 6 weeks of age. The influence of maternally derived antibodies has not been studied in detail and it is therefore recommended that calves vaccinated before 12 weeks of age are re-vaccinated at 12 weeks of age.

## **9. Advice on correct administration**

Shake well before use.

## **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. 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.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Vm: 60021/3018

Cardboard carton containing a 5-dose vial of lyophilisate, supplied with a vial containing 25 ml (5 doses) of suspension.

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](http://www.gov.uk).

## **16. Contact details**

Marketing authorisation 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  
Tel: +353 (0) 1 256 9800

Manufacturer responsible for batch release:

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
Belgium

**17. Other information**

POM-V  
For animal treatment only.

*Gavin Hall*

Approved: 06 November 2025