

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal nasal spray, lyophilisate and solvent for suspension for cattle

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

### Active substances:

#### Lyophilisate

Bovine parainfluenza virus 3 (PI3V), strain RLB 103, live  $10^{5.0} - 10^{8.6}$  CCID<sub>50</sub>.

Bovine respiratory syncytial virus (BRSV), strain 375, live  $10^{5.0} - 10^{7.2}$  CCID<sub>50</sub>.

CCID<sub>50</sub>: Cell Culture Infective Dose 50%.

### Excipients:

Qualitative composition of excipients and other constituents
<b>Lyophilisate:</b>
Buffered lactose solution
Gelatin solution
Casein hydrolysate solution
HALS medium
<b>Solvent:</b>
Sodium chloride
Water for injections

Lyophilisate: slightly whitish to yellowish freeze-dried pellet.

Solvent: clear colourless liquid, free from visible impurities.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle.

### 3.2 Indications for use for each target species

#### For vaccination with Rispoval RS+PI3 IntraNasal only:

For active immunisation of maternally derived antibody positive or negative calves from 9 days of age against BRSV and PI3V, to reduce the mean titre and duration of excretion of both viruses.

Onset of immunity: 5 days for BRSV and 10 days for PI3V after a single vaccination.

Duration of immunity: 12 weeks after a single vaccination. The duration of protective immunity against the PI3V fraction may be reduced in MDA positive calves vaccinated before 3 weeks of age.

For primary vaccination using Rispoval RS/Pi3 IntraNasal and booster vaccination with Rispoval 2/BRSV + Pi3\*, refer to the Rispoval 2/BRSV Pi3\* product information for specific details on indications.

\* Where this veterinary medicinal product is authorised.

### 3.3 Contraindications

None.

### 3.4 Special warnings

Vaccinate healthy animals only.

Animals should preferably be vaccinated at least 10 days before a period of stress or high infection risk like re-grouping or transport of animals, or at the start of the autumn season. To achieve optimal results, it is recommended to vaccinate all the calves within the same herd.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Vaccinal viruses can spread from vaccinated to non-vaccinated calves and may cause a serological response, but without causing clinical signs. In laboratory experiments based on the data using 3 week-old animals, shedding was observed for BRSV and PI3V up to 11 and 7 days respectively after vaccination with one dose containing the maximal virus content.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction(e.g. anaphylactic-type reaction)
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Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

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.

### 3.8 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.

### **3.9 Administration routes and dosage**

Dose: 2 ml.

Route: nasal use.

Reconstitution of the vaccine:

Reconstitute the 1 dose and 5 dose presentations by aseptically adding the solvent to the vial containing the lyophilisate. Shake well before use.

Reconstitute the 25 dose presentation by mixing the lyophilised fraction with the solvent in 2 steps:

1. Inject 10 ml of the solvent 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 solvent in the liquid fraction vial.

Shake well before use.

Reconstituted product: pink to orange liquid, which might contain a loose resuspendable sediment.

Vaccination programme:

Basic vaccination: A single dose of 2 ml of reconstituted vaccine should be given using the intranasal applicator available from Zoetis to cattle from the age of 9 days. It is recommended to change applicators between animals to avoid transmitting infectious organisms.

For primary vaccination using Rispoval RS/Pi3 IntraNasal and booster vaccination with Rispoval 2/BRSV + Pi3\*, refer to the Rispoval 2/BRSV Pi3\* product information for specific details on vaccination programme.

\* Where this veterinary medicinal product is authorised.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

In colostrum-deprived animals vaccinated before 3 weeks of age with a 10-fold overdose of vaccine, transient temperature increase, nutritional scour, abnormal faeces and demeanour were observed.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

*To be completed nationally.*

### **3.12 Withdrawal periods**

Zero days.

## **4. IMMUNOLOGICAL INFORMATION**

### **4.1 ATCvet code: QI02AD07**

To stimulate active immunity against BRSV and PI3V.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale (5 and 25 doses presentations): 2 years.

Shelf life of the veterinary medicinal product as packaged for sale (1 dose presentation): 1 year.

Shelf life after reconstitution according to directions: 2 hours.

### **5.3 Special precautions for storage**

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

Do not freeze.

Protect from light.

### **5.4 Nature and composition of immediate packaging**

Cardboard box with 1 glass vial of 5 or 25 doses of lyophilisate accompanied by 1 glass vial containing respectively 10 or 50 ml of solvent. Both vials have rubber stopper and aluminium cap.

Plastic box with 5 glass vial(s) of 1 dose of lyophilisate accompanied by 5 glass vial(s) containing 2 ml of solvent. Both vials have rubber stopper and aluminium cap.

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

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 national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

*To be completed nationally.*

## **7. MARKETING AUTHORISATION NUMBER(S)**

*To be completed nationally.*

## **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: *To be completed nationally.*

## **9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

*To be completed nationally.*

## **10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

[AT, BE, BG, CZ, DE, EE, ES, FR, HU, IT, LT, LU, LV, NL, PL, PT, RO, SK, UK(NI)]: Veterinary medicinal product subject to prescription.

[IE]: Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****CARDBOARD BOX (5 OR 25 DOSES)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Rispoval RS+PI3 IntraNasal nasal spray, lyophilisate and solvent for suspension

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 2 ml dose contains:

Bovine parainfluenza virus 3 (PI3V), strain RLB 103, live	$10^{5.0} - 10^{8.6}$ CCID <sub>50</sub> .
Bovine respiratory syncytial virus (BRSV), strain 375, live	$10^{5.0} - 10^{7.2}$ CCID <sub>50</sub> .

**3. PACKAGE SIZE**

1 x 5 doses  
1 x 25 doses

**4. TARGET SPECIES**

Cattle

**5. INDICATIONS**

*To be completed nationally.*  
<For products not subject to veterinary prescription.>

**6. ROUTES OF ADMINISTRATION**

Nasal use.

**7. WITHDRAWAL PERIODS**

Withdrawal period: Zero days.

**8. EXPIRY DATE**

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

<b>9. SPECIAL STORAGE PRECAUTIONS</b>
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Store and transport refrigerated.  
Do not freeze.  
Protect from light.

<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
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Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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*To be completed nationally.*

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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*To be completed nationally.*

<b>15. BATCH NUMBER</b>
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Lot {number}

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****PLASTIC BOX (1 DOSE)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Rispoval RS+PI3 IntraNasal nasal spray, lyophilisate and solvent for suspension

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 2 ml dose contains:

Bovine parainfluenza virus 3 (PI3V), strain RLB 103, live	$10^{5.0} - 10^{8.6}$ CCID <sub>50</sub> .
Bovine respiratory syncytial virus (BRSV), strain 375, live	$10^{5.0} - 10^{7.2}$ CCID <sub>50</sub> .

**3. PACKAGE SIZE**

5 x 1 dose

**4. TARGET SPECIES**

Cattle

**5. INDICATIONS**

*To be completed nationally.*  
<For products not subject to veterinary prescription.>

**6. ROUTES OF ADMINISTRATION**

Nasal 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.

<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
--

Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
--

For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
--

Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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*To be completed nationally.*

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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*To be completed nationally.*

<b>15. BATCH NUMBER</b>
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Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE****LABEL ON GLASS VIAL – LYOPHILISATE (5 OR 25 DOSES)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Rispoval RS+PI3 IntraNasal nasal spray, lyophilisate and solvent for suspension

**2. STATEMENT OF ACTIVE SUBSTANCES**

PI3V, strain RLB 103, live       $10^{5.0} - 10^{8.6}$  CCID<sub>50</sub>.  
BRSV, strain 375, live       $10^{5.0} - 10^{7.2}$  CCID<sub>50</sub>.

5 doses  
25 doses

**3. TARGET SPECIES**

Cattle

**4. ROUTES OF ADMINISTRATION**

Nasal use.  
Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal period: Zero days.

**6. EXPIRY DATE**

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

**7. SPECIAL STORAGE PRECAUTIONS**

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

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

*To be completed nationally.*

<b>9. BATCH NUMBER</b>
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Lot {number}

<b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</b>
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<b>LABEL ON GLASS VIAL – LYOPHILISATE (1 DOSE)</b>
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<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
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Rispoval RS+PI3 IntraNasal

<b>2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES</b>
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Live BRSV, and bovine PI3V

1 dose

<b>3. BATCH NUMBER</b>
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Lot {number}

<b>4. EXPIRY DATE</b>
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Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS****LABEL ON GLASS VIAL – SOLVENT (2, 10 OR 50 ML)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Rispoval RS+PI3 IntraNasal solvent

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

1 dose (2 ml)  
5 doses (10 ml)  
25 doses (50 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 RS+PI3 IntraNasal nasal spray, lyophilisate and solvent for suspension for cattle

### 2. Composition

Each 2 ml dose contains:

#### Active substances:

##### Lyophilisate

Bovine parainfluenza virus 3 (PI3V), strain RLB 103, live  $10^{5.0} - 10^{8.6}$  CCID<sub>50</sub>.

Bovine respiratory syncytial virus (BRSV), strain 375, live  $10^{5.0} - 10^{7.2}$  CCID<sub>50</sub>.

CCID<sub>50</sub>: Cell Culture Infective Dose 50%.

Lyophilisate: slightly whitish to yellowish freeze-dried pellet.

Solvent: clear colourless liquid, free from visible impurities.

### 3. Target species

Cattle.

### 4. Indications for use

#### For vaccination with Rispoval RS+Pi3 IntraNasal only:

For active immunisation of maternally derived antibody positive or negative calves from 9 days of age against BRSV and PI3V, to reduce the mean titre and duration of excretion of both viruses.

Onset of immunity: 5 days for BRSV and 10 days for PI3V after a single vaccination.

Duration of immunity: 12 weeks after a single vaccination. The duration of protective immunity against the PI3V fraction may be reduced in MDA positive calves vaccinated before 3 weeks of age.

For primary vaccination using Rispoval RS/Pi3 IntraNasal and booster vaccination with Rispoval 2/BRSV + Pi3\*, refer to the Rispoval 2/BRSV Pi3\* product information for specific details on indications.

\* Where this veterinary medicinal product is authorised.

### 5. Contraindications

None.

### 6. Special warnings

#### Special warnings:

Vaccinate healthy animals only.

Animals should preferably be vaccinated at least 10 days before a period of stress or high infection risk like re-grouping or transport of animals, or at the start of the autumn season. To achieve optimal results, it is recommended to vaccinate all the calves within the same herd.

Special precautions for safe use in the target species:

Vaccinal viruses can spread from vaccinated to non-vaccinated calves and may cause a serological response, but without causing clinical signs. In laboratory experiments based on the data using 3 week-old animals, shedding was observed for BRSV and PI3V up to 11 and 7 days respectively after vaccination with one dose containing the maximal virus content.

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:

In colostrum-deprived animals vaccinated before 3 weeks of age with a 10-fold overdose of vaccine, transient temperature increase, nutritional scour, abnormal faeces and demeanour were observed.

Special restrictions for use and special conditions for use:

*To be completed nationally.*

Major incompatibilities:

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

## **7. Adverse events**

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):
Hypersensitivity reaction [e.g. anaphylactic-type reaction (severe allergic reaction)]

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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Dose: 2 ml.

Route: nasal use.

Vaccination programme:

Basic vaccination: A single dose of 2 ml of reconstituted vaccine should be given using the intranasal applicator available from Zoetis to cattle from the age of 9 days. It is recommended to change applicators between animals to avoid transmitting infectious organisms.

For primary vaccination using Rispoval RS/Pi3 IntraNasal and booster vaccination with Rispoval 2/BRSV + Pi3\*, refer to the Rispoval 2/BRSV Pi3\* product information for specific details on vaccination programme.

\* Where this veterinary medicinal product is authorised.

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

### Reconstitution of the vaccine:

Reconstitute the 1 dose and 5 dose presentations by aseptically adding the solvent to the vial containing the lyophilisate. Shake well before use.

Reconstitute the 25 dose presentation by mixing the lyophilised fraction with the solvent in 2 steps:

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

Shake well before use.

Reconstituted product: pink to orange liquid, which might contain a loose resuspendable sediment.

## **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: use within 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> <or> <pharmacist> how to dispose of medicines no longer required.

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

AT, BE, BG, CZ, DE, EE, ES, FR, HU, IT, LT, LU, LV, NL, PL, PT, RO, SK, UK(NI): Veterinary medicinal product subject to prescription.

IE: Veterinary medicinal product not subject to prescription.

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

*To be completed nationally.*

Cardboard box with 1 glass vial of 5 or 25 doses of lyophilisate accompanied by 1 glass vial containing respectively 10 or 50 ml of solvent. Both vials have rubber stopper and aluminium cap.

Plastic box with 5 glass vial(s) of 1 dose of lyophilisate accompanied by 5 glass vial(s) containing 2 ml of solvent. Both vials have rubber stopper and aluminium cap.

Not all pack sizes may be marketed.

**15. Date on which the package leaflet was last revised**

*To be completed nationally.*

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

**16. Contact details**

Marketing authorisation holder <and contact details to report suspected adverse reactions>:  
*To be completed nationally.*

Manufacturer responsible for batch release:

Zoetis Belgium  
Rue Laid Burniat 1  
1348 Louvain-La-Neuve  
Belgium

<Local representatives <and contact details to report suspected adverse reactions>:>  
*To be completed nationally (if needed).*

**17. Other information**

To stimulate active immunity against BRSV and PI3V.