PARTICULARS TO APPEAR ON THE OUTER PACKAGE - BOX

Rispoval RS+PI3 IntraNasal – 5 or 25 dose box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Powder:
Active substance:
- Bovine Respiratory Syncytial virus (BRSV), modified live, strain 375, $\geq 10^{5.0}$ and $\leq 10^{7.2}$ $CCID_{50}$
- Parainfluenza type 3 virus (PI3V), modified live, strain RLB103, $\geq 10^{5.0}$ and $\leq 10^{8.6}$ $CCID_{50}$.

Diluent:
- Water for injection
- Sodium chloride, 18 mg per 2 ml

3. PHARMACEUTICAL FORM

Powder and diluent for suspension for intranasal application.

4. PACKAGE SIZE

1 x 5 dose powder vial + 1 x 5 dose liquid (10 ml).
1 x 25 dose powder vial + 1 x 25 dose liquid (50 ml).

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose 2 ml. Intranasal route. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero Days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry Date

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C - 8°C). Do not freeze.
Protect from light - Once reconstituted, use within 2 hours

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

Dispose of waste 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.

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

Keep out of 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 42058/4130

17. MANUFACTURER'S BATCH NUMBER

Batch No.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE – PLASTIC BOX

Rispoval RS+PI3 IntraNasal – 1 dose box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Powder (Active substance):	**Diluent:**
BRSV, modified live strain ≥$10^{5.0}$ and ≤$10^{7.2}$ $CCID_{50}$	Sodium chloride: 18 mg
PI3V, modified live strain ≥$10^{5.0}$ and ≤$10^{8.6}$ $CCID_{50}$	Water for injection: 2 ml

3. PHARMACEUTICAL FORM

Powder and diluent for suspension for intranasal application.

4. PACKAGE SIZE

5 x 1 dose powder vial + 5 x 1 dose liquid (2 ml).

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose 2 ml. Intranasal route. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero Days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry Date

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C - 8°C). Do not freeze.
Protect from light - Once reconstituted, use within 2 hours

12. SPECIAL 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.

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

Keep out of 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 42058/4130

17. MANUFACTURER'S BATCH NUMBER

Batch No.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - LABEL

Rispoval RS+PI3 IntraNasal – 5 or 25 dose label – Powder

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal
Powder

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Bovine Respiratory Syncytial virus (BRSV), modified live strain 375, $\geq 10^{5.0}$ and $\leq 10^{7.2}$ $CCID_{50}$.
Parainfluenza type 3 virus (PI3V), modified live strain RLB103, $\geq 10^{5.0}$ and $\leq 10^{8.6}$ $CCID_{50}$.

3. PHARMACEUTICAL FORM

Powder

4. PACKAGE SIZE

5 doses.
25 doses.

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

Zero Days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C - 8°C). Do not freeze. Protect from light. For full instructions see package insert.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

Keep out of 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 42058/4130

17. MANUFACTURER'S BATCH NUMBER

Batch No.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Rispoval RS+PI3 IntraNasal – 1 dose label - Powder

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal
Powder

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

BRSV, modified live strain PI3V, modified live strain

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

Intranasal

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - DILUENT

Rispoval RS+PI3 IntraNasal – 1, 5 or 25 dose Diluent (2, 10 or 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal
STERILE DILUENT

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Form: Natr.chlorid. 0.9% - Aqua pro inject. pro 2 ml.
Form: Natr.chlorid. 0.9% - Aqua pro inject. pro 10 ml.
Form: Natr.chlorid. 0.9% - Aqua pro inject. pro 50 ml.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS "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 42058/4130

17. MANUFACTURER'S BATCH NUMBER

Batch No.

PACKAGE LEAFLET
Rispoval RS+PI3 IntraNasal

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS+PI3 IntraNasal

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

A powder containing Parainfluenza type 3 virus (PI3V), modified live strain RLB103, $\geq 10^{5.0}$ and $\leq 10^{8.6}$ $CCID_{50}$*, and Bovine Respiratory Syncytial virus (BRSV), modified live strain 375, $\geq 10^{5.0}$ and $\leq 10^{7.2}$ $CCID_{50}$*, supplied with sterile diluent (water for injection and sodium chloride, 18 mg per 2 ml) for reconstitution.
Slightly coloured powder and clear colourless diluent for suspension for intranasal application.
*$CCID_{50}$: Cell Culture Infective Dose 50%

4. INDICATION(S)

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 protective immunity: 5 days for BRSV and 10 days for PI3V after a single vaccination.
Duration of protective immunity: 12 weeks following a single dose. The duration of protective immunity against the PI3V fraction may be reduced in MDA positive calves vaccinated before 3 weeks of age.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Published evidence shows that on rare occasions repeated exposure to RSV may trigger hypersensitivity reactions. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

Reconstitute the 1 dose and 5 dose presentations by aseptically adding all the liquid to the vial containing the powder components. Shake well before use.

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

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

Shake well before use.

Vaccination programme:
A single dose of 2 ml of reconstituted vaccine should be given intranasally to cattle from the age of 9 days, using the applicators provided. It is recommended to change applicators between animals to avoid transmitting infectious organisms.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute the vaccine by aseptically adding all the liquid to the vial containing the powder. Shake well. The reconstituted, dissolved vaccine is a pinkish suspension.

10. WITHDRAWAL PERIOD

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. Once reconstituted use within 2 hours.

12. SPECIAL WARNING(S)

Special precautions for use in animals: For animal treatment only. Vaccinate only healthy animals. Animals should be preferably vaccinated at least 10 days before a period of stress or high infection 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. 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.

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.

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

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

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

1dose.
5 doses.
25 doses.

Not all pack sizes may be marketed

Approved 10 January 2020