PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Rispoval RS – Outer Carton
1x 10ml (5 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS

2. STATEMENT OF ACTIVE SUBSTANCES

Vaccine containing BRSV

COMPOSITION:
Freeze-dried fraction:
- Live attenuated Bovine Respiratory Syncytial Virus, strain RB94, minimum $10^{5.5}$ $CCID_{50}$ per dose.

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

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection.

4. PACKAGE SIZE

1 x 5 dose freeze-dried vial + 1 x 5 dose diluent (10 ml)

1 x 10 ml (5 doses)

5. TARGET SPECIES

For cattle

6. INDICATION(S)

INDICATIONS: For the active immunisation of calves to reduce infections and clinical signs associated with BRSV.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSE: 2 ml

ROUTE: Intramuscular.
Reconstitute the entire contents of the freeze-dried vial with the entire contents of the diluent vial.

VACCINATION PROGRAMME:
Animals older than 4 months of age: Give 2 doses three to four weeks apart.
Animals from 7 days to 4 months of age: Give 2 doses with a three to four week interval, with a third dose at 4 months.

8. WITHDRAWAL PERIOD(S)

WITHDRAWAL PERIOD: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Consult the package insert for further information, contra-indications and warnings etc.

10. EXPIRY DATE

Exp date:
Reconstituted vaccine should be used immediately.

11. SPECIAL STORAGE CONDITIONS

STORAGE:
Store between +2°C and +8°C. Do not freeze.

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

Consult the package insert for further information, contra-indications and warnings etc.

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

FOR ANIMAL TREATMENT ONLY.

POM-V
UK Authorised Veterinary Medicinal Product.

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

KEEP OUT OF 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 42058/4129

17. MANUFACTURER'S BATCH NUMBER

Lot No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Rispoval RS – Vial label
5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS
For cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

COMPOSITION:
Freeze-dried fraction:
- Live attenuated Bovine Respiratory Syncytial Virus, strain RB94, minimum $10^{5.5}$ $CCID_{50}$ per dose.

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

5 doses

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot no:

7. EXPIRY DATE

Exp. Date:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
Keep out of reach of children.
Store between +2°C and +8°C. Do not freeze.
For full instructions see package insert.

MA Holder:
Zoetis UK Limited, Surrey

To be supplied only on veterinary prescription,

Vm 42058/4129
POM-V

PACKAGE LEAFLET:
Rispoval RS

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS

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

A freeze-dried pellet, each dose containing live attenuated Bovine Respiratory Syncytial Virus, strain RB94, minimum $10^{5.5}$ $CCID_{50}$* supplied with a vial of sterile diluent (water for injection and sodium chloride) for reconstitution.
*$CCID_{50}$ = Cell Culture Infectious Dose 50

4. INDICATION(S)

For the active immunisation of calves to reduce infections and clinical signs associated with BRSV.
Onset of immunity occurs by 7 days after vaccination, as demonstrated serologically.
Studies have shown a duration of immunity of at least 4 months.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy animals.

6. ADVERSE REACTIONS

Anaphylactic reactions may occasionally occur. Where necessary, appropriate antihistamine treatment should be instituted.

7. TARGET SPECIES

Cattle from 7 days of age.

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

Reconstitute each 5 dose vial with 10 ml sterile diluent. Immediately give 2 ml reconstituted vaccine intramuscularly.

Vaccination programme:
Animals older than 4 months of age:
Give 2 doses three to four weeks apart.

Animals from 7 days to 4 months of age:
Give two doses with a three to four week interval, with a third dose at 4 months of age. The third dose is required due to the possible interference from high titres of maternally derived antibodies during the first few months of life. An interval of at least 14 days should be observed between the second and third injection.
Ideally animals should be vaccinated during the autumn or at housing prior to the period of a greatest risk. Maximum protection occurs when the whole herd is vaccinated.

9. ADVICE ON CORRECT ADMINISTRATION

As far as possible take reasonable aseptic precautions in reconstituting and withdrawing vaccine. Reconstituted vaccine should be used immediately. Do not use chemically sterilised syringes or needles, as these will affect the effectiveness of the vaccine.

10. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store between +2°C and +8°C. Do not freeze.
Keep out of reach of children.

12. SPECIAL WARNING(S)

Rispoval RS can be used during pregnancy
No information is available on the safety and efficacy from the concurrent use of this vaccine with any other product except Rispoval Pasteurella (inactivated *Pasteurella haemolytica* vaccine), Tracherine (live infectious bovine rhinotracheitis vaccine) and Imuresp RP (live infectious bovine rhinotracheitis and Parainfluenza type 3 vaccine). It is therefore recommended that no vaccines other than these should be administered within 14 days before and after vaccination with this product.
Do not mix with any other immunological product except the diluent supplied.
No reactions other than those listed above have been observed following administration of a ten times overdose with Rispoval RS.
Operator warning:
In case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical attention showing a copy of the package insert.

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

Empty or part-used vials should be burned or immersed in an approved disinfectant before disposal.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2020

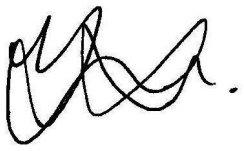
15. OTHER INFORMATION

For animal treatment only.

LEGAL CATEGORY
POM-V
UK Authorised Veterinary Medicinal Product

PACKAGE QUANTITIES
Packs containing a 5 dose vials supplied with a vial containing 10 ml of sterile diluent.

MARKETING AUTHORISATION NUMBER
Vm 42058/4129



Approved: 01 May 2020