ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 4

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (5 ml) contains:
Suspension:
- Infectious Bovine Rhinotracheitis (IBR) virus min. GMT $2\log_2$,
- Bovine Viral Diarrhoea (BVD) virus min. GMT 5 $\log_2$.

Lyophilisate:
- Bovine Parainfluenza 3 (PI3) virus min. $10^{5.0}$ $CCID_{50}$.
- Bovine Respiratory Syncytial Virus (BRSV) min. $10^{5.0}$ $CCID_{50}$.

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

For cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

5 ml IM. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Exp date:
Shelf life after reconstitution: 2 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material 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.

POM-V
To be supplied only on veterinary prescription.

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

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

Vm 42058/4125

17. MANUFACTURER'S BATCH NUMBER

Lot No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Rispoval 4 – Lyophisate vial label
5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 4

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Lyophilisate containing BRSV, ≥ $10^{5.0}$ $CCID_{50}$, and PI3 virus, ≥ $10^{5.0}$ $CCID_{50}$.
Only to be mixed with the suspension fraction of Rispoval 4.

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

5 doses

4. ROUTE(S) OF ADMINISTRATION

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.

To be supplied only on veterinary prescription,
Vm 42058/4125
POM-V

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

5 doses (25 ml)

4. ROUTE(S) OF ADMINISTRATION

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.

To be supplied only on veterinary prescription,
Vm 42058/4125
POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Rispoval 4

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 4

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

Each 5 ml contains:

Suspension fraction:
- Infectious Bovine Rhinotracheitis (IBR) virus, strain Cooper, minimum GMT $2\log_2$.
- Bovine Viral Diarrhoea (BVD) virus, cytopathic strain 5960 and non-cytopathic strain 6309, minimum 5 $\log_2$.

Lyophilisate fraction:
- Bovine Parainfluenza 3 (PI3) virus, thermosensitive strain RLB103, minimum $10^{5.0}$ $CCID_{50}$.
- Bovine Respiratory Syncytial Virus (BRSV), strain 375, minimum $10^{5.0}$ $CCID_{50}$

Adjuvant:
Aluminium hydroxide, maximum 5.2 mg per ml

4. INDICATION(S)

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 leucopaenia and viraemia caused by the Bovine Viral Diarrhoea (BVD) virus Type I, cytopathic and non-cytopathic strains.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Very rarely, administration of the vaccine may be followed by a mild transient reaction at the injection site up to 0.5 cm and completely resolved within 15 days.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

DOSE: 5 ml

ROUTE: Intramuscular.
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.

Shake well before use.

VACCINATION SCHEME:
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

None

10. WITHDRAWAL PERIOD(S)

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.
Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL WARNING(S)

Pregnancy:
Do not use during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be used 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.
Incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2020

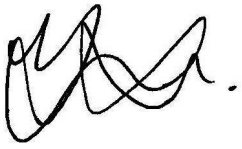
15. OTHER INFORMATION

LEGAL CATEGORY:
POM-V
To be supplied only on veterinary prescription

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

MARKETING AUTHORISATION NUMBER:
Vm 42058/4125

FOR ANIMAL TREATMENT ONLY



Approved: 01 May 2020