SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 4 lyophilisate and suspension for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml dose contains:

Active substances:
Suspension fraction:
Infectious Bovine Rhinotracheitis (IBR) virus, strain Cooper, ≥ GMT 2 log_2*

Bovine Viral Diarrhoea (BVD) virus, cytopathic strain 5960,
and Bovine Viral Diarrhoea (BVD) virus, non-cytopathic strain 6309, ≥ GMT 5 log_2*

* 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 $10^{5.0}$ $CCID_{50}$

Bovine Respiratory Syncytial Virus (BRSV) strain 375,
minimum titre at the end of shelf life, > or equal $10^{5.0}$ $CCID_{50}$

Adjuvant:
Aluminium hydroxide (2 % Al_2O_3) ≤ 5.2 mg Al_20_3 per ml

Excipients:

Qualitative composition of excipients and other constituents
Buffered lactose
Gelatin
Casein hydrolysate
HALS medium

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. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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 virus (BVDV) Type I, cytopathic and non-cytopathic strains.

Duration of immunity: at least 6 months.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[1]

[1] Mild, transient. Up to 0.5 cm and completely resolved within 15 days.

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 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:
Do not use during the whole pregnancy.

3.8 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.

3.9 Administration routes and dosage

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

When the lyophilised plug 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.

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

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 over the age of 3 months, via the intramuscular route.

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.

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

None.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AH

Live and inactivated viral vaccines.

To stimulate active immunity against BRSV, PI3, IBR (BHV-1) and cytopathic and non-cytopathic strains of BVD Type I viruses in cattle.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years (lyophilisate).
Shelf life of the veterinary medicinal product as packaged for sale: 3 years (suspension).
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 containing 5 doses of lyophilisate accompanied by 1 glass vial containing 5 doses (25 ml) of suspension.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5171

8. DATE OF FIRST AUTHORISATION

31 May 2001

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

September 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall

Approved: 06 November 2025