# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 4

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml dose contains:
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

For the full list of excipients, see Section 6.1.

## 3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

## 4. CLINICAL PARTICULARS

### 4.1 Target Species

Cattle

### 4.2 Indications for Use, Specifying the 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 leucopaenia and viraemia caused by the Bovine Viral Diarrhoea virus (BVDV) Type I, cytopathic and non-cytopathic strains. A duration of immunity of at least 6 months has been demonstrated.

## 4.3 Contraindications

None

## 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

Not applicable.

## 4.6 Adverse reactions (frequency and seriousness)

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).

## 4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy.

## 4.8 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.

## 4.9 Amounts to be administered and administration route

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.

*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.

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No symptoms other than those mentioned in Section 4.6.

## 4.11 Withdrawal Period

Zero days.

## 5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live and inactivated viral vaccines.
**ATCVet code:** QI02AH
To stimulate active immunity against BRSV, PI3, IBR (BHV-1) and cytopathic and non-cytopathic strains of BVD Type I viruses in cattle.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Aluminium hydroxide.

### 6.2 Major incompatibilities

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

### 6.3 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: 2 hours.

### 6.4 Special Precautions for Storage

Store and transport refrigerated (2°C - 8°C). Do not freeze.
Protect from light.

### 6.5 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.

### 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

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

## 7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

## 8. MARKETING AUTHORISATION NUMBER

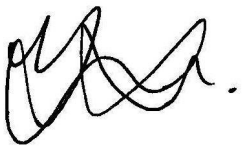
Vm 42058/4125

## 9. DATE OF THE FIRST AUTHORISATION

31 May 2001

## 10. DATE OF REVISION OF THE TEXT

May 2020



Approved: 01 May 2020