# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval RS

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of Rispoval RS contains the following:

**Active substances:**
Live attenuated Bovine Respiratory Syncytial Virus, strain RB94: minimum: $10^{5.5}$ $CCID_{50}$

**Diluent:**

| | |
|---|---|
| Sodium chloride | 18 mg |
| Water for injection qsd | 2 ml |

See section 6.1 for full list of excipients.

## 3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle from 7 days of age.

### 4.2 Indications for use, specifying the target species

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.

## 4.3 Contraindications

Do not use in unhealthy animals.

**Special warnings for each target species**

Maximum protection occurs when the whole herd is vaccinated.

## 4.4 Special precautions for use

i) Special precautions for use in animals

None.

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

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.

## 4.5 Adverse reactions (frequency and seriousness)

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

## 4.6 Use during pregnancy, lactation or lay

Can be used during pregnancy.

## 4.7 Interaction with other medicinal products and other forms of interaction

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 / Parainfluenza type 3 vaccine). 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.

## 4.8 Amounts to be administered and administration route

*Dosage and route of administration:*
Reconstitute each 5-dose vial with 10 ml of sterile diluent. Immediately give 2 ml reconstituted vaccine intramuscularly.

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.

*Vaccination programme:*
In animals 4 months of age or older, give 2 doses three to four weeks apart.

In younger animals, 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.

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

No reactions other than those quoted under Section 4.6 have been observed following administration of ten times the recommended dose.

## 4.10 Withdrawal period

Zero days.

# 5. IMMUNOLOGICAL PROPERTIES

For the stimulation of an active immunity against bovine respiratory syncytial virus.

**ATCVet Code:** QI02AD04

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Gentamycin
Neomycin

### 6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except the diluent supplied.

### 6.3 Shelf life

24 months.
Vaccine should be used immediately after reconstitution.

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

Cardboard carton containing a type I glass vial containing 5 doses of freeze-dried component closed with a rubber stopper and sealed with an aluminium cap, and a type I glass vial containing 10 ml of diluent.

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

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

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER

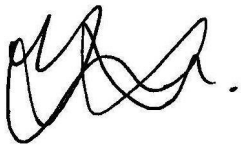
Vm 42058/4129

## 9. DATE OF REVIEW OF THE AUTHORISATION

13 October 2005

## 10. DATE OF REVISION OF THE TEXT

May 2020



Approved: 01 May 2020