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 ingredient(s)
Live attenuated Bovine Respiratory Syncytial Virus, strain RB94 :
minimum :$10^{5.5}$ $CCID_{50}$ per dose.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder for suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and calves from 7 days of age.

4.2 Indications for use, specifying the target species

RISPOVAL RS is a live attenuated vaccine designed to reduce the respiratory symptoms caused by Bovine Respiratory Syncytial Virus in cattle.
Use of the vaccine results in a reduction in viral shedding.
Duration of immunity is 4 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Do not vaccinate animals for at least one month after cessation of corticosteroid treatment. The presence of maternally derived antibodies may affect the efficacy of Rispoval RS. When vaccinating calves of less than 4 months of age, an extra injection is required (see Section 4.9).

Unhealthy animals should not be vaccinated.

Maximum protection occurs when the whole herd is vaccinated.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
No special precautions are needed for other livestock, vaccinators and stock handlers. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

On rare occasions, an anaphylactic response to injection may occur and, where necessary, symptomatic antihistaminic treatment should be instituted.

4.7 Use during pregnancy, lactation or lay

Can be safely used in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

This vaccine can safely be administered, but not mixed with, Rispoval Pasteurella. Except for Rispoval Pasteurella, no information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

One dose = 2 ml.
Aseptically reconstitute each vial of lyophilised BRSV with the corresponding volume of diluent, e.g. for a 5 dose vial, transfer 10 ml of diluent to the vial. After introduction of the diluent, shake well and immediately administer 2 ml reconstituted vaccine by intramuscular injection.

Use aseptic precautions in reconstituting and withdrawing vaccine. Do not use chemically sterilised syringes or needles as these will affect the effectiveness of the vaccine.

Basic vaccination scheme:

In animals 4 months of age or older, administer 2 doses three to four weeks apart.

In animals less than 4 months of age, administer 2 doses three to four weeks apart, and a third dose at 4 months of age. This is necessary due to the possible interference from high titres of maternally derived antibodies during the first few months of life.

Ideally animals should be vaccinated during the autumn or at housing prior to the period of a greatest risk.

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

No effects other than those stated in section 4.6 have been observed following administration of an overdose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Bovine Respiratory Syncytial Virus.

ATC Vet Code QI02AD04

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Diluent Sodium chloride

FG Stabilizer

HAL-MEM medium

Water for injection

6.2 Incompatibilities

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

6.3 Shelf-life

24 months
Reconstituted vaccine should be used immediately.

6.4 Special precautions for storage

Store and transport refrigerated +2°C to +8°C. Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

The vaccine is filled in 1, 5 and 25 dose glass vials type I.
The diluent is filled in 1-dose (2 ml), 5-dose (10 ml) and 25-dose (50 ml) vials.
Both vials have a butyl rubber stopper and an aluminium cap.
Not all vial sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A
2nd Floor, Building 10
Cherrywood Business Park
Co. Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10387/063/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st June 2003

Date of last renewal: 30th April 2008

10 DATE OF REVISION OF THE TEXT

March 2017