# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 3 BRSV Pi3 BVD
Lyophilisate and suspension for suspension for injection for cattle

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (4 ml) contains:

**Active substance(s):**
*Lyophilised fraction*

| | |
|---|---|
| Parainfluenza 3 virus, modified live strain RLB 103 | $10^{5.0}$ to $10^{8.6}$ $CCID_{50}$ |
| Bovine Respiratory Syncytial Virus, modified live strain 375 | $10^{5.0}$ to $10^{7.2}$ $CCID_{50}$ |

*Liquid fraction*
Bovine Virus Diarrhoea Virus Type 1, inactivated strains 5960 (cytopathic) and 6309 (non-cytopathic), to induce a GMT seroneutralisation titre in guinea pigs of at least 3.0 $log_2$

**Adjuvant:**

| | |
|---|---|
| Alhydrogel 2% | 0.8 ml (equivalent to 24.36 mg of aluminium hydroxide) |

$CCID_{50}$ = Cell Culture Infectious Dose 50%

**Excipients:**
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

Active immunisation of calves from 12 weeks of age to:

- reduce virus excretion and the clinical signs caused by bovine Pi3 virus,
- reduce virus excretion caused by BRSV infection,
- reduce virus excretion and the severity of the leucopenia induced by BVDV type 1 infection.

Onset of immunity: 3 weeks after vaccination

Duration of immunity: 6 months (demonstrated by challenge studies) after vaccination for BRSV and BVDV Type 1. Duration of immunity has not been established for bovine Pi3 virus.

Efficacy has not been demonstrated against BVDV Type 2 strains.

## 4.3 Contraindications

None.

## 4.4 Special warnings for each target species

Vaccinate healthy animals only.

## 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
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)

Transient and mild hyperthermia which can last for 2 days and t a transient, minor local inflammation reaction of up to 0.5 cm which disappears within 15 days can occur very commonly after administration of the vaccine. Very rarely, the vaccine may cause hypersensitivity reactions. In case of anaphylactic reaction, symptomatic treatment should be provided.

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

Pregnancy and lactation:

The safety and efficacy of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

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

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided 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 lyophilized fraction.

When the lyophilised fraction and liquid fraction are filled in equally sized vials, inject the entire liquid fraction into the lyophilized fraction 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:

1. Inject 10ml of the liquid fraction on the lyophilised plug in the lyophilized fraction vial.
2. Shake well and extract the reconstituted lyophilised fraction from the lyophilized fraction vial and mix with the liquid fraction in the liquid fraction vial.

Shake well before use.

Administer one dose (4 ml) of the reconstituted vaccine by intramuscular route according to the following vaccination scheme:

First injection: from 12 weeks of age.
Second injection: 3 to 4 weeks later.

Animals should be preferably vaccinated at least 3 weeks before a period of stress or high infection risk like re-grouping or transport of animals, or the start of autumn season. If protection against BRSV and BVDV type 1 is required, then animals should be re-vaccinated after 6 months. The duration of immunity of the Pi3 component is not known.

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

Reactions after administration of an overdose of vaccine are not different from those after the single dose.

### 4.11 Withdrawal period(s)

Zero days.

## 5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live and inactivated viral vaccines.
ATC vet code: QI02AH

To stimulate an active immunity against Pi3, BRSV and BVDV type 1.

The vaccine has a broad cross-neutralising ability against various current European strains of BVDV type I as measured *in vitro* by virus neutralisation test. Cross neutralisation at a lower level has also been demonstrated to BVDV Type 2 strains.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Buffered lactose solution
Gelatin solution
Casein hydrolysate solution
HALS medium

### 6.2 Major incompatibilities

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

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf-life after reconstitution according to directions: 2 hours.

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

- Type I glass vial containing 5 or 25 doses (20 or 100 ml) liquid fraction, closed with chlorobutyl rubber stopper and sealed with aluminium cap.
- Type I glass vial containing 5 or 25 doses of lyophilised fraction, closed with bromobutyl rubber stopper and sealed with aluminium cap.

Cardboard box with 1 vial of lyophilised fraction (5 doses) and 1 vial of liquid fraction (20 ml).
Cardboard box with 1 vial of lyophilised fraction (25 doses) and 1 vial of liquid fraction (100 ml).

Not all pack sizes may be marketed

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

Any unused veterinary medicinal product or waste materials 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

Leatherhead
Surrey
KT22 7LP

## 8. MARKETING AUTHORISATION NUMBER

Vm 42058/4124

## 9. DATE OF FIRST AUTHORISATION

03 May 2005

## 10. DATE OF REVISION OF THE TEXT

10 January 2020

Approved 10 January 2020