# 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

Each 4 ml dose contains:

**Active substances:**

**Lyophilisate:**

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

**Suspension:**

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 $log_2$

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

**Adjuvant:**

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

**Excipients:**

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Lyophilisate: slightly coloured freeze-dried pellet.
Suspension: slightly coloured turbid liquid which might contain a loose sediment. On shaking well, the sediment is easily resuspended.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle.

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

For 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 and

- reduce virus excretion and the severity of the leucopenia induced by BVDV Type 1 infection.

Onset of immunity: 3 weeks.

Duration of immunity: 6 months (demonstrated by challenge studies) 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.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable

## 4.6 Adverse reactions (frequency and seriousness)

Cattle:

| | |
|---|---|
| Very common (>1 animal / 10 animals treated): | Hyperthermia[1]<br>Injection site inflammation[2] |
| Very rare (<1 animal / 10,000 animals treated, including isolated reports): | Hypersensitivity reaction, anaphylactic-type reaction[3] |

[1]Transient and mild; can last for 2 days.
[2]Transient and minor; up to 0.5 cm which disappears within 15 days.
[3]In case of anaphylactic reaction, symptomatic treatment should be provided.

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.

## 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 made on a case by case basis.

## 4.9 Amount(s) to be administered and administration route

**Dose**: 4 ml.
**Route**: intramuscular.
**Reconstitution of the vaccine**:
Reconstitute the vaccine by adding the suspension to the vial containing the lyophilisate.

When the lyophilisate and suspension are filled in equally sized vials, inject the entire suspension into the vial containing the lyophilisate.

When the lyophilisate is filled in a smaller vial size than the suspension, the reconstitution of the vaccine is carried out in 2 steps:

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

Shake well before use.

Reconstituted product is a slightly coloured turbid liquid which might contain a loose sediment which is easily resuspended on shaking well.

**Vaccination scheme:**

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

*Basic immunisation:* two doses, each of 4 ml, 3-4 weeks apart from 12 weeks of age.

*Booster vaccinations:* if protection against BRSV and BVDV Type 1 is required, then animals should be revaccinated after 6 months.

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. The duration of immunity of the Pi3 component is not known.

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

No adverse events other than those mentioned in section 4.6 were observed after administration of an overdose of the vaccine.

### 4.11 Withdrawal period(s)

Zero days.

## 5. IMMUNOLOGICAL PROPERTIES

**Pharmacotherapeutic group:** Live and inactivated viral vaccines.

**ATCvet 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 1 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

**Lyophilisate:**
Buffered lactose solution
Gelatin solution
Casein hydrolysate solution
**Suspension:**
HALS medium

### 6.2 Major incompatibilities

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

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 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

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

Cardboard box with 1 vial of lyophilisate (5 doses) and 1 vial of suspension (20 ml).
Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of suspension (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

Medicines should not be disposed of via wastewater.

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
Springfield Drive
Leatherhead
Surrey
KT22 7LP

## 8. MARKETING AUTHORISATION NUMBER

Vm 42058/5135

## 9. DATE OF FIRST AUTHORISATION

03 May 2005

## 10. DATE OF REVISION OF THE TEXT

June 2024

**PROHIBITION OF SALE, SUPPLY AND/OR USE**
Not applicable.

## 11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

*Gavin Hall*

Approved 22 June 2024