Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Rispoval 2 / BRSV + Pi3 Lyophilisate and solvent for suspension for injection for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 4 ml contains:

Active substances:
Lyophilisate
Bovine Parainfluenza 3 virus (Pi3V), modified live strain RLB 103 $10^{5.0}$ - $10^{8.6}$ $CCID_{50}$
Bovine Respiratory Syncytial Virus (BRSV), modified live strain 375 $10^{5.0}$ - $10^{7.2}$ $CCID_{50}$

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

Adjuvant:
Aluminium hydroxide gel 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 and solvent for suspension for injection.

Lyophilisate: Slightly whitish to yellowish freeze-dried pellet.
Solvent: Pinkish to orange-brown turbid liquid, which might contain 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

Active immunisation of cattle from 12 weeks of age to:
- reduce virus excretion caused by bovine Pi3 virus and
- reduce virus excretion caused by BRSV infection.

Onset of immunity:	3 weeks after the basic vaccination scheme
Duration of immunity:	6 months after the basic vaccination scheme for BRSV. Duration of immunity has not been established for bovine Pi3 virus.

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 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 interactions

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 solvent to the vial containing the lyophilisate.

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

When the lyophilisate is filled in a smaller vial size than the solvent, the reconstitution of the vaccine is carried out in 2 steps:
1. Inject 10 ml of the solvent 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 solvent in the liquid fraction vial.

Shake well before use.

Reconstituted product: pink-orange turbid suspension with loose sediment.

Dose: 4 ml

Route: Intramuscular use
Vaccination scheme:
Basic vaccination: Two doses of Rispoval 2, 3-4 weeks apart from 12 weeks of age.
Re-vaccination: If continued protection against BRSV is required, then animals should be revaccinated after 6 months. The duration of immunity of the Pi3 component is not known.

Animals should preferably be vaccinated at least 3 weeks before a period of stress or high infection risk such as re-grouping or transport of animals, or the start of autumn season.

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 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for bovidae, live viral vaccines for cattle.
ATC vet code: QI02AD07

To stimulate an active immunity against Pi3 and BRSV.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Lactose Monohydrate
Potassium hydrogen phosphate
Dipotassium phosphate
Monopotassium L-glutamate
Water, purified
Gelatin
Casein hydrolysate solution
HALS medium

Solvent:
Aluminium hydroxide gel
HALS medium

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent 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: use immediately.

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) of solvent, 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 solvent (20 ml).
Cardboard box with 1 vial of lyophilisate (25 doses) and 1 vial of solvent (100 ml).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/100/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of firsth authorisation: 19 February 2021

10 DATE OF REVISION OF THE TEXT