Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVALTO RESPI INTRANASAL, nasal spray, lyophilisate and solvent for suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Lyophilisate:	
Active substances:	
Bovine parainfluenza 3 virus (PI3V), modified live virus, strain Bio 23/A	105.0 – 107.5 TCID50
Bovine respiratory syncytial virus (BRSV), modified live virus, strain Bio 24/A	104.0– 106.0 TCID50

TCID50 – a 50% infectious dose for tissue cultures

Solvent:	
Phosphate buffered saline	2 ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, lyophilisate and solvent for suspension

Appearance before reconstitution:
The lyophilisate has a porous structure, off-white or yellowish colour.
The solvent is clear, colourless.
Appearance after reconstitution: opalescent liquid of yellowish to pinkish colour.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the active immunisation of calves from the age of 10 days against bovine respiratory syncytial virus (BRSV) and bovine parainfluenza 3 virus (PI3V), to reduce the quantity and duration of nasal excretion of both viruses.
Onset of immunity: 10 days after vaccination

Duration of immunity: 12 weeks after vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The laboratory efficacy studies have demonstrated that the presence of maternally derived antibodies at the time of vaccination had no impact on vaccine efficacy in young animals.
Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinated calves can excrete the vaccine strains BRSV and PI3V for up to 6 days after vaccination. Therefore, the spread of the vaccine virus from vaccinated to unvaccinated calves cannot be excluded. Animals should be vaccinated at least 10 days before the critical period of stress or high risk of infection, such as rearrangement or transport of animals, or in early autumn. To achieve optimal results, it is recommended to vaccinate all calves of the herd.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Very commonly, a slight and transient nasal discharge may occur the first three days after vaccination without any adverse consequence for in-contact animals.
The local reactions observed and their frequency relate to observations following administration of an overdose under controlled laboratory conditions.

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

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 products. 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 Amounts to be administered and administration route

Nasal use.
Reconstitute the vaccine by aseptically adding the supplied solvent into the vial containing the lyophilised component. Mix well.
Required volume of the reconstituted vaccine is either drawn up from the bottle by syringe with a needle, the needle is then replaced by the intranasal applicator provided and the vaccine is administered or left in the bottle and administered via a multi-dose applicator that can deliver each dose through the intranasal applicator. The intranasal applicator is used to spray the required volume of the vaccine into the animal´s nostrils. The applicator used should spray the vaccine in the form of 30 µm to 100 µm droplets.

Vaccination schedule:
Administer one dose (2 ml) of the reconstituted vaccine intranasally (1 ml of the vaccine into each nostril) to calves from 10 days of age using an intranasal applicator. It is recommended to use a new applicator for each animal, in order to prevent the transmission of infection.

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

No adverse effect other than that mentioned in section 4.6. (Adverse Reactions).

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group; Immunologicals; Immunologicals for bovidae; Cattle, live viral vaccines.
ATC vet code: QI02AD07 Bovine respiratory syncytial virus + bovine parainfluenza virus
To stimulate the active immunity against BRSV and PI3V.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Trometamol
Edetic acid
Sucrose
Dextran 70

Solvent:
Sodium chloride
Potassium chloride
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for injection

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 (lyophilisate) as packaged for sale: 2 years.
Shelf-life of the solvent as packaged for sale: 4 years.
Shelf life after reconstitution according to directions: 2 hours

6.4 Special precautions for storage

Lyophilisate and solvent:
Store and transport refrigerated (2°C – 8°C).
Do not freeze.
Protect from direct sunlight.

Reconstituted vaccine:
Store below 25°C. Do not freeze

6.5 Nature and composition of immediate packaging

Lyophilisate: type I glass bottle (5 doses) with a rubber stopper and aluminium cap.
Solvent: type I glass bottle of 10 ml with a rubber stopper and an aluminium cap.

Pack size:
Cardboard box:
1 x 5 doses of lyophilised vaccine + 1x10 ml of solvent

Plastic box with a lid:
5 x 5 doses of lyophilised vaccine + 5x10 ml of solvent

Intranasal applicators are packaged separately. Applicators are distributed together with the vaccine.
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 products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/029/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 April 2018

10 DATE OF REVISION OF THE TEXT

December 2018