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 virus 3, strain Bio 23/A, live	$10^{5.0} – 10^{7.5}$ $TCID_{50}$
Bovine respiratory syncytial virus, strain Bio 24/A, live	$10^{4.0} – 10^{6.0}$ $TCID_{50}$

$TCID_{50}$ – a 50% infectious dose for tissue cultures

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Trometamol
Edetic acid
Sucrose
Dextran 70
Solvent: (phosphate buffered saline)
Sodium chloride
Potassium chloride
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for injection

Appearance before reconstitution:
The lyophilisate has a spongy consistency, white to yellowish colour.
The solvent is clear, colourless.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the active immunisation of calves from the age of 10 days against bovine respiratory syncytial virus (BRSV) and bovine parainfluenza virus 3 (BPIV-3), 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.

3.3 Contraindications

None.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccinated calves can excrete the vaccine strains BRSV and BPIV-3 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction*

*may require appropriate symptomatic treatment

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 its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy and lactation.

3.8 Interactions 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 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.

3.9 Administration routes and dosage

Nasal use.
For 1-dose and 5-dose presentations, reconstitute the vaccine by aseptically adding the supplied solvent into the vial containing the lyophilised component. Mix well.
For the 10-dose presentation, reconstitute the vaccine in two steps. First transfer a part of the diluent into the vial containing the lyophilised component. Mix well. Transfer the mixture into the vial

containing the rest of the diluent. Mix well.
Appearance after reconstitution: colourless or yellowish liquid with a slight opalescence.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

A slight and transient nasal discharge was observed the first three days after the administration of a 10-fold overdose without any adverse consequence for in-contact animals.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATC vet code: QI02AD07

Immunologicals for bovidae; Cattle, live viral vaccines.
To stimulate the active immunity against BRSV and BPIV-3.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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

5.3 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.

5.4 Nature and composition of immediate packaging

Lyophilisate: type I glass bottle (1, 5 or 10 doses) with a rubber stopper and aluminium cap.
Solvent: 3 ml (1 dose) or 10 ml (5 doses) type I glass bottle or 20 ml (10 doses) type II glass bottle with a rubber stopper and an aluminium cap.

Pack size:
Cardboard box:
1 x 5 doses of lyophilised vaccine + 1 x 10 ml of solvent
1 x 10 doses of lyophilised vaccine + 1 x 20 ml of solvent

Plastic box with a lid:
5 x 1 dose of lyophilised vaccine + 5 x 2 ml of solvent
5 x 5 doses of lyophilised vaccine + 5 x 10 ml of solvent

Intranasal applicators are packaged separately. Applicators are distributed together with the vaccine.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/029/003

8. DATE OF FIRST AUTHORISATION

13/04/2018

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03/04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database. (*https://medicines.health.europa.eu/veterinary*).