

## **B. PACKAGE LEAFLET**

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BOVALTO RESPI INTRANASAL, nasal spray, lyophilisate and solvent for suspension  
(In SE NO DK: BOVALTO RESPI 2, nasal spray, lyophilisate and solvent for suspension)

### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorization holder:

To be completed nationally

Manufacturer responsible for batch release:

Bioveta, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

In SE NO DK: BOVALTO RESPI 2, nasal spray, lyophilisate and solvent for suspension

### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One dose (2 ml) contains:

#### **Lyophilisate:**

#### **Active substances:**

Bovine parainfluenza 3 virus (PI3V), modified live virus, strain Bio 23/A	$10^{5.0} - 10^{7.5}$ TCID <sub>50</sub>
Bovine respiratory syncytial virus (BRSV), modified live virus, strain Bio 24/A	$10^{4.0} - 10^{6.0}$ TCID <sub>50</sub>

TCID<sub>50</sub> – a 50% infectious dose for tissue cultures

#### **Solvent:**

2 ml

Phosphate buffered saline

Appearance before reconstitution:

The lyophilisate has a porous structure, off-white or yellowish colour.

The solvent is clear, colourless.

### 4. INDICATIONS

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.

### 5. CONTRAINDICATIONS

None.

## **6. ADVERSE REACTIONS**

A hypersensitivity reaction may very rarely occur, which may require appropriate symptomatic treatment.

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}

## **7. TARGET SPECIES**

Cattle

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

### Dosage:

2 ml of the reconstituted vaccine per animal.

### Route of administration:

Nasal use.

### 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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Nasal use.

Appearance after reconstitution: opalescent liquid of yellowish to pinkish colour.

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.

## **10. WITHDRAWAL PERIOD(S)**

Zero days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP

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

## **12. SPECIAL WARNING(S)**

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.

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.

Pregnancy and lactation:

Do not use during pregnancy and lactation.

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 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.

Overdose (symptoms, emergency procedures, antidotes)

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

Incompatibilities:

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

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

To be completed nationally.

**15. OTHER INFORMATION**

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.

Package 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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.