PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. Cardboard box with printing:
1 x 5 doses – glass vial 1 x 5 doses of lyophilised vaccine + 1 x 10 ml of solvent
1 x 10 doses – glass vial 1 x 10 doses of lyophilised vaccine + 1 x 20 ml of solvent

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 dose (2 ml):
Lyophilisate:
Bovine parainfluenza 3 virus (PI3V), modified live virus, strain Bio 23/A $10^{5.0}$ – $10^{7.5}TCID_{50}$
Bovine respiratory syncytial virus (BRSV), modified live virus, strain Bio 24/A $10^{4.0}$ – $10^{6.0}TCID_{50}$

3. PACKAGE SIZE

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
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

4. TARGET SPECIES

Cattle

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Nasal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from direct sunlight.
Store the reconstituted vaccine below 25°C.

Keep the container in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

14. MARKETING AUTHORISATION NUMBERS

Vm 08327/5006

15. BATCH NUMBER

Lot:

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1 dose (glass vial of lyophilised vaccine)
5 doses (glass vial of lyophilised vaccine)
10 doses (glass vial of lyophilised vaccine)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVALTO RESPI INTRANASAL - Lyophilisate

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1 d.
5 d.
10 d. 

2 ml
10 ml
20 ml

3. BATCH NUMBER

Lot:

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT/SOLVENT LABEL

1 dose (3ml glass vial with 2 ml of solvent)
5 doses (10 ml glass vial with 10 ml of solvent)
10 doses (20 ml glass vial with 20 ml of solvent)

1. NAME OF THE DILUENT/SOLVENT

BOVALTO RESPI INTRANASAL - Solvent

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2 ml
10 ml
20 ml

3. ROUTES OF ADMINISTRATION

4. STORAGE CONDITIONS

5. BATCH NUMBER

Lot

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

One dose (2 ml) contains:

Lyophilisate:
Active substances:
Bovine parainfluenza 3 virus (PI3V), modified live virus, strain Bio 23/A $10^{5.0}$ – $10^{7.5}$ $TCID_{50}$
Bovine respiratory syncytial virus (BRSV), modified live virus, strain Bio 24/A $10^{4.0}$ – $10^{6.0}$ $TCID_{50}$

$TCID_{50}$ – 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.

3. TARGET SPECIES

Cattle

4. INDICATIONS FOR USE

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. SPECIAL WARNING(S)

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.

Special precautions for safe use in the target species:
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:
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.

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

7. 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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system.

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

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. The expiry date refers to the last day of that month.

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 PRECAUTIONS FOR DISPOSAL

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Package 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

Not all pack sizes may be marketed.

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15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

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

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

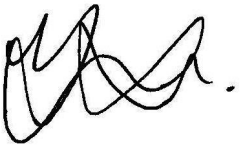
Manufacturer responsible for batch release:
Bioveta, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic

17. OTHER INFORMATION

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.

For Animal Treatment Only.

Intranasal applicators are packaged separately. Applicators are distributed together with the vaccine.



Approved: 30 December 2022