

ANNEXE III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1x10 ml, 10x10 ml, 1x50 ml, 1x100 ml/ cardboard box
10x10 ml / covered plastic box with 10 cavities

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVALTO Respi 4 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose (2ml):

Inactivated bovine respiratory syncytial virus, strain BIO-24	RP* \geq 1
Inactivated bovine parainfluenza 3 virus, strain BIO-23	RP* \geq 1
Inactivated bovine viral diarrhoea virus, strain BIO-25	RP* \geq 1
Inactivated <i>Mannheimia haemolytica</i> , serotype A1 strain DSM 5283	RP* \geq 1

* Relative potency

3. PACKAGE SIZE

1x10 ml
10x10 ml
1x50 ml
1x100 ml

4. TARGET SPECIES

Cattle.



5. INDICATIONS

For products not subject to veterinary prescription

For active immunisation of cattle in the absence of maternally derived antibodies against:

- parainfluenza 3 virus, to reduce virus excretion due to infection,
- bovine respiratory syncytial virus, to reduce virus excretion due to infection,
- bovine viral diarrhoea virus, to reduce virus excretion due to infection
- *Mannheimia haemolytica* serotype A1, to reduce clinical signs and lung lesions.

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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 OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 04491/3006

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVALTO Respi 4 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose (2 ml):

Inactivated bovine respiratory syncytial virus, strain BIO-24 RP* \geq 1

Inactivated bovine parainfluenza 3 virus, strain BIO-23 RP* \geq 1

Inactivated bovine viral diarrhoea virus, strain BIO-25 RP* \geq 1

Inactivated *Mannheimia haemolytica*, serotype A1 strain DSM 5283 RP* \geq 1

* Relative potency

100 ml

3. TARGET SPECIES

Cattle.



4. ROUTES OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle: 10 ml, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVALTO Respi 4



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 ml

50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

BOVALTO Respi 4 suspension for injection

2. Composition

One dose (2 ml) contains:

Active substances:

Inactivated bovine respiratory syncytial virus, strain BIO-24	RP* \geq 1
Inactivated bovine parainfluenza 3 virus, strain BIO-23.....	RP* \geq 1
Inactivated bovine viral diarrhoea virus, strain BIO-25	RP* \geq 1
Inactivated <i>Mannheimia haemolytica</i> , serotype A1 strain DSM 5283.....	RP* \geq 1

* RP = Relative potency in comparison with the reference serum obtained after vaccination of guinea pigs with a vaccine batch that has successfully passed the challenge test in the target animals.

Adjuvants:

Aluminium hydroxide	8.0 mg
Quillaja saponin (Quil A)	0.4 mg

Excipients:

Thiomersal.....	0.2 mg
Formaldehyde	1.0 mg at most

Appearance: pinkish liquid with sediment.

3. Target species

Cattle.

4. Indications for use

For active immunisation of cattle in the absence of maternally derived antibodies against:

- parainfluenza 3 virus, to reduce virus excretion due to infection,
- bovine respiratory syncytial virus, to reduce virus excretion due to infection,
- bovine viral diarrhoea virus, to reduce virus excretion due to infection,
- *Mannheimia haemolytica* serotype A1, to reduce clinical signs and lung lesions.

Onset of immunity: 3 weeks.

Duration of immunity: 6 months.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

Safety and efficacy studies were performed in sero-negative calves. The efficacy of the vaccination by challenge has not been demonstrated in presence of antibodies. The level of antibody responses may be reduced by the presence of maternal antibodies. In the presence of maternal antibodies, timing of initial vaccination of calves should be planned accordingly.

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.

Pregnancy and lactation:

Can be used 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 product. 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:

No adverse events except those mentioned under section 'Adverse events' were observed after the administration of a 2-fold overdose.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):

Injection site swelling*

Common (1 to 10 animals / 100 animals treated):

Hyperthermia**

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type reactions***
Injection site pain****

*This swelling could reach up to 10 cm or more in diameter and may be associated with pain, and usually progressively reduces and disappears within 6 weeks after vaccination).

**Transient and slight, higher after the second injection (1.5°C at most) lasting up to 3 days after vaccination.

*** Appropriate symptomatic treatment should be administered.

**** Associated with injection site swelling.

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Subcutaneous use.

Dose: 2 ml administered subcutaneously.

Primary vaccination:

Calves from non-immune dams: two doses three weeks apart from 2 weeks of age.

For calves from immune dams or where the immune status of the dam is unknown, the vaccination scheme should be adapted at the discretion of the veterinarian to take into account potential interference of maternally derived antibodies with the response to vaccination.

Revaccination:

Administer one dose six months after completion of the primary vaccination scheme.

The efficacy of revaccination was demonstrated by measurement of the serological response and has not been assessed by challenge.

9. Advice on correct administration

Warm before use to a temperature of 15 °C to 25 °C and shake the contents of the bottle.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C)
Do not freeze.
Protect from light.

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 after first opening the immediate packaging: 10 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number: Vm 04491/3006

Pack sizes:

1 x 10 ml, 10 x 10 ml
1 x 50 ml, 1 x 100 ml

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 273, 55216 Ingelheim Am Rhein, Germany

Manufacturer responsible for batch release:

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

Local representative and contact details to report suspected adverse reactions:

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

17. Other information

The vaccine is filled in Type I (for 10 ml) or Type II glass bottles (for 50 and 100 ml) and plastic bottles (for 10, 50, or 100 ml) compliant with Ph.Eur., closed with a chlorobutyl elastomer closure and secured with an aluminium cap.

Approved 25 November 2024
Gavin Hall