B. PACKAGE LEAFLET
BOVALTO Respi 4 suspension for injection

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 locally

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 4 suspension for injection

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

One dose (2 ml) contains:

Active substances:
- Inactivated bovine respiratory syncytial virus, strain BIO-24  \( \text{RP}^* \geq 1 \)
- Inactivated bovine parainfluenza 3 virus, strain BIO-23  \( \text{RP}^* \geq 1 \)
- Inactivated bovine viral diarrhea virus, strain BIO-25  \( \text{RP}^* \geq 1 \)
- Inactivated *Mannheimia haemolytica*, serotype A1 strain DSM 5283  \( \text{RP}^* \geq 1 \)

* \( \text{RP}^* \) = 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

Suspension for injection
Appearance: pinkish liquid with sediment.

4. INDICATIONS

For active immunization 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. ADVERSE REACTIONS

A localised swelling may be very commonly observed at the injection site. 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. 
A transient slight increase in body temperature may commonly appear which is higher after the second injection (1.5°C at most) lasting up to 3 days after vaccination. 
Anaphylactic-type reactions may very rarely occur after vaccination. In such cases, appropriate symptomatic treatment should be administered.

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

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 PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C)
Use within 10 hours after opening.
Do not freeze.
Protect from light.

12. SPECIAL WARNINGS

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
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 (symptoms, emergency procedures, antidotes):
No undesirable effects except those mentioned under section 6. (Adverse reactions) were observed.

Incompatibilities:
Do not mix with any other 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 locally.

15. OTHER INFORMATION

The vaccine is filled in Type I or type II glass bottles and plastic bottles compliant with Ph.Eur., closed with a chlorobutyl elastomer closure and secured with an aluminium cap.

Pack size:
1 x 10 ml, 10 x 10 ml
1 x 50 ml, 1 x 100 ml

Not all pack sizes may be marketed.