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e-mail: obchod@bioveta.cz

B. PACKAGE LEAFLET

BIOVETA, a. s. Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic,
e-mail: registrace@bioveta.cz

PACKAGE LEAFLET:
BioBos Respi 3 suspension for injection for cattle

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

Marketing authorization holder and manufacturer responsible for batch release:
Bioveta, a. s., Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioBos Respi 3 suspension for injection for cattle

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

Each vaccination dose (2 ml) contains:

Active substances:

Bovine respiratory syncytial virus (BRSV) inactivated, strain BIO-24 RP ≥ 1*

Bovine parainfluenza 3 virus (PI3V) inactivated, strain BIO-23 RP ≥ 1*

Mannheimia (Pasteurella) haemolytica inactivated, strain DSM 5283, serotype 1A RP ≥ 1*

* RP = Relative potency (ELISA) 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 hydrated for adsorption	8.0 mg
Quillaja saponin (Quil A)	0.4 mg

Excipients:

Thiomersal	0.2 mg
Formaldehyde 35% solution	max. 1 mg

Pinkish liquid with sediment.

4. INDICATION

For active immunisation of cattle against:
- bovine parainfluenza 3 virus, to reduce infection,
- bovine respiratory syncytial virus, to reduce infection and clinical signs,

- germs of *Mannheimia* (*Pasteurella*) *haemolytica* serotype A1, to reduce clinical signs and lung lesions.

Onset of immunity:
3 weeks

Duration of immunity:
6 months

Safety and efficacy studies were performed in sero-negative calves.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances, to the adjuvants or to any of the excipients.

6. ADVERSE REACTIONS

A localised swelling may be very commonly observed at the injection site after vaccination. 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 reactions)
- 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.

7. TARGET SPECIES

Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Vaccine dose – 2 ml
The vaccine is administered subcutaneously.

Basic immunisation:

Calves from non-immune dams: 2 injections 3 weeks apart from 2 weeks of age

Calves from immune dams: 2 injections 3 weeks apart from 3 months of age

Revaccination:

In problematic breeds, another revaccination is recommended within a period of 6 months after basic immunisation, possibly before risky period in particular breed (e.g. transfer of animals, change of the stabling system, etc.).

9. ADVICE ON CORRECT ADMINISTRATION

Heat up the vaccine before use to a temperature of 15 to 25°C and shake the content of the vial.
Vaccinate only healthy animals.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2°C – 8°C).
Protect from frost.
Protect from light.
Do not use this this veterinary medicinal product after the expiry date which is stated on the label.
Shelf-life after first opening the immediate packaging: 10 hours.

12. SPECIAL WARNINGS

Special precautions for use in animals:
The basic immunization should be started in time so that the protection has been fully developed until the start of animals' risk period. The basic immunization of calves must be finished before their joint stabling or during quarantine.

It is recommended to vaccinate all animals in the herd, unless the vaccination is contraindicated in some animals, to minimize the infection stress. Omission of individual animals helps preserve and transfer pathogens and develop the disease in the herd.

The level of antibody responses may be reduced by maternal antibodies obtained from the mothers in calves up to 3 months of age.

Respiratory infections in calves are often connected with a poor hygiene practices. Therefore, the total improvement of hygiene practices is important for ensuring a good immunization effect in vaccinated animals.

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.

Use during pregnancy, 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 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

15. OTHER INFORMATION

The vaccine is filled in glass vials of hydrolytic class I or II and plastic vials compliant with Ph.Eur.,
closed with rubber chlorobutyl puncturable stopper, secured with aluminium seal.

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.