B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

BioBos BTV 3 suspension for injection for sheep and cattle

2. Composition

Each 1 ml dose contains:

Bluetongue virus, serotype 3, strain Bio-93:BTV3, inactivated	10 - 320 ELISA units*

*The amount of inactivated antigen was determined using an ELISA method.

Adjuvants:	
Aluminium hydroxide	2.25 – 2.75 mg
Quillaja saponin (Quil A)	0.2 mg
Excipient:	
Thiomersal	0.085 – 0.115 mg

White to pinkish liquid with sediment present.

3. Target species

 : sheep  : cattle

4. Indications for use

Sheep:
Active immunisation to reduce viraemia and to prevent clinical signs caused by bluetongue virus (BTV) serotype 3.

Onset of immunity: 3 weeks after the primary vaccination course.
Duration of immunity: has not been established.

Cattle:
Active immunisation to prevent viraemia and to prevent clinical signs caused by bluetongue virus (BTV) serotype 3.

Onset of immunity: 3 weeks after the primary vaccination course.
Duration of immunity: 6 months.

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.

Basic immunisation should be started in time so that protection has fully developed by the beginning of the risk period for the animal (related to the appearance of the main vectors of the disease – biting midges).

High levels of maternal antibodies negatively affect the formation of post-vaccination antibodies, which may affect the level of antibodies after vaccination. These maternally derived antibodies usually disappear within 3 months in lambs and within 2.5 months of age in cattle.

If used in other domestic and wild ruminant species that are considered at risk of infection, its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of animals prior to mass vaccination. The level of efficacy for other species may differ from that observed in sheep and cattle.

Pregnancy, lactation and fertility:
Can be used during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation.
The safety of the vaccine has not been established in breeding males. In this category of animals, the vaccine should be used only according to the benefit/risk assessment by the responsible veterinarian and/ or national Competent Authorities on the current vaccination policies against bluetongue virus (BTV).

Interactions 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 decided on a case by case basis.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product containing serotype 3 must first consult the relevant Member State ´s competent authority on the current vaccination policies, as these activities may be prohibited in aMember State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Sheep and cattle:

- **Undetermined frequency**: Injection site swelling and elevated temperature.

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 should 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, routes and method of administration

Administer one dose of 1 ml, subcutaneously in sheep, intramuscularly in cattle, according to the following vaccination scheme:

Primary vaccination
In sheep: one injection from 1 month of age in naive animals.

In cattle:
- 1st injection: from 1 month of age in naive animals.
- 2nd injection: 3 weeks after the first injection.

Revaccination
Not established.

9. Advice on correct administration

Apply usual aseptic procedures.

Shake gently immediately before use. Avoid bubble formation, as this can be irritating at the site of injection. The entire content of the bottle should be used immediately after broaching and during the same procedure. Avoid multiple broaching of vials.

Before use the vaccine should be warmed to 15-25°C.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2ºC – 8ºC).
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 the 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA number:

Plastic box with 10 wells:
Box of 10 vials of 10 doses (10 x 10 ml)

Carton box:
Box of 1 vial of 10 doses (1 x 10 ml)
Box of 1 vial of 50 doses (1 x 50 ml)
Box of 1 vial of 100 doses (1 x 100 ml)

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union medicinal products database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorization holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Bioveta a.s.,
Komenského 212/12 Ivanovice
na Hané, 683 23
Czech Republic
Tel: +420 517 318 911
e-mail: reklamace@bioveta.cz

17. Other information

The vaccine stimulates active immunity against bluetongue virus serotype 3 in the vaccinated animal.

EXCEPTIONAL CIRCUMSTANCES:
Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.