SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BULTAVO 3 suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:
Inactivated bluetongue virus serotype 3 (strain Bio-93:BTV3) ..... ≥ 10 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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Formaldehyde 35%	≤ 0.7 mg
Thiomersal	0.085 – 0.115 mg
Sodium chloride	
Water for injections	

White to pinkish liquid with sediment present.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and cattle.

3.2 Indications for use for each target species

Sheep:

Active immunisation to reduce viraemia and to prevent clinical signs and mortality caused by bluetongue virus serotype 3.

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

Cattle:

Active immunisation against bluetongue virus serotype 3.

Onset of immunity: not established.
Duration of immunity: not established.

3.3 Contraindications

None.

3.4 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 of age 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep and cattle:

Undetermined frequency:	Injection site swelling Elevated temperature

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian. Reports should be sent, preferably via a veterinarian, to the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation and fertility:
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 these categories 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).

3.8 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.

3.9 Administration routes and dosage

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The safety of an overdose has not been established.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

The veterinary medicinal product has been allowed for emergency use. The efficacy of the vaccine has not been tested in cattle. Therefore, the vaccine should be used according to the benefit/risk assessment by the responsible veterinarian.

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product containing serotype 3 must first consult the relevant National competent authority on the current vaccination policies, as these activities may be prohibited nationally on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AA02 (sheep) and QI02AA08 (cattle)

To stimulate active immunity against bluetongue virus in the vaccinated animal.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2ºC – 8ºC).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

HDPE bottle containing 10 doses of 1 ml with chlorobutyl elastomer closure.
HDPE bottle containing 50 doses of 1 ml with chlorobutyl elastomer closure.

Pack sizes:
Box of 1 bottle of 10 doses (1 x 10 ml)
Box of 1 bottle of 50 doses (1 x 50 ml)

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Non-authorized product.
Marketed by Boehringer Ingelheim Vetmedica GmbH.

Allowance for emergency use according to Art. 110 of Reg. (EU) 2019/6 or Part 3, Sch. 4, Para. 4 of the UK VMRs 2013.
Assessment based on customised requirements for documentation.

7. MARKETING AUTHORISATION NUMBER(S)

Not applicable (see section 6).

8. DATE OF FIRST AUTHORISATION

Not applicable.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

04/09/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.