

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC-3 suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substance:

Bluetongue virus (BTV), serotype 3, strain BTV-3/NET2023, inactivated $10^{6.5}$ CCID₅₀
*

* CCID₅₀: 50% cell culture infective dose equivalent to titre prior inactivation.

Adjuvants:

Aluminium hydroxide6 mg
Purified saponin (Quil A).....0.05 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Thiomersal	0.1 mg
Sodium chloride	
Disodium phosphate	
Potassium phosphate	
Water for injections	

White or pinkish-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and cattle.

3.2 Indications for use for each target species

Sheep

For active immunisation of sheep to reduce the viraemia, mortality and clinical signs caused by the serotype 3 of the bluetongue virus.

Onset of immunity: 3 weeks after completion of the primary vaccination scheme.

Duration of immunity: not established.

Cattle

For active immunisation of cattle to reduce the viraemia against the serotype 3 of the bluetongue virus.

Onset of immunity: 3 weeks after completion of the primary vaccination scheme.

Duration of immunity: not established.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

No information is available on the use of the vaccine in seropositive sheep and cattle, including those with maternal antibodies.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep

Very common (>1 animal / 10 animals treated):	Injection site swelling ¹ Injection site nodule ²
Common (1 to 10 animals / 100 animals treated):	Elevated temperature ³
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Loss of appetite Hypersensitivity reaction

¹Painless, diameter up to 4 cm, for up to 9 days, transforms into a nodule.

²Painless, diameter up to 4 cm, recedes within 14 days.

³Up to 1 °C, for up to 72 hours.

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling ¹ Injection site nodule ²
Rare (1 to 10 animals / 10,000 animals treated):	Elevated temperature ³
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Loss of appetite Hypersensitivity reaction

¹Painless, diameter up to 9 cm, for up to 6 days, transforms into a nodule.

²Painless, diameter 0.5 to 9 cm, recedes in 25% of animals within 21 days.

³Up to 1 °C, for up to 24 hours.

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

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy in ewes and cows.

Lactation:

No negative impact on the milk-yield using the vaccine in lactating ewes and cows is expected.

Fertility:

The safety of the vaccines 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 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

Shake well before use. Avoid multiple vial broaching. Avoid introduction of contamination.

Subcutaneous use.

Primary vaccination

Sheep from 2 months of age:

Administer two doses of 2 mL subcutaneously 3 weeks apart.

Cattle from 2 months of age:

Administer two doses of 4 mL subcutaneously 3 weeks apart.

Revaccination

Not established

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

After the administration of a double dose, no adverse reactions other than those described in section 3.6 were observed.

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

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State 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

To stimulate active immunity of sheep and cattle against bluetongue virus serotype 3.

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: 18 months.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles of 52 mL, 100 mL or 252 mL with bromobutyl stoppers and aluminium seals.

Package sizes:

Cardboard box with 1 bottle containing 52 mL
Cardboard box with 1 bottle containing 100 mL
Cardboard box with 1 bottle containing 252 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

CZ Vaccines S.A.U.

7. MARKETING AUTHORISATION NUMBER

Vm 30824/5002

8. DATE OF FIRST AUTHORISATION

04 April 2025

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

April 2025

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.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 24 April 2025