SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC-3 suspension for injection for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of vaccine contains:

Active substance:

Bluetongue virus, serotype 3, strain BTV-3/NET2023, inactivated ..... $10^{6.5}$ $CCID_{50}$ *

* $CCID_{50}$: 50% cell culture infective dose equivalent to titre prior inactivation

Adjuvants:
Aluminium hydroxide .....6 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 injection	

White or pinkish-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

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

Onset of immunity: 21 days 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: 21 days after completion of the primary vaccination scheme.

Duration of immunity: not established yet.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Occasionally, the presence of maternally-derived antibodies in sheep of minimum recommended age might interfere with the protection induced by the vaccine.

No information is available on the use of the vaccine in cattle with maternally derived antibodies.

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 cattle and sheep.

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 nodule[1]
Common(1 to 10 animals / 100 animals treated) :	Hyperthermia[2]
Very rare (< 1 animals / 10,000 animals treated, including isolated reports)	Loss of appetite Hypersensitivity reaction

[1]A painless nodule of 3.5 cm which decreases progressively over time and normally disappears within 14 days
[2]A transient increase in rectal temperature not exceeding 1ºC is common. It lasts no longer than 24 to 72 hours.

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site nodule[1]
Rare (1 to 10 animals / 10,000 animals treated)	Hyperthermia[2]

Very rare (< 1 animals / 10,000 animals treated, including isolated reports)	Loss of appetite Hypersensitivity reaction

[1]A painless nodule of 0.5 to 9 cm which decreases progressively over time and normally disappears within 21 days.

Note: Adverse events based on those reported for BLUEVAC vaccines containing serotypes 8, 1 and 4 antigens and confirmed by studies performed with BLUEVAC-3.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to 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 and efficacy of the vaccines has not been established in breeding males (sheep and cattle). 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).

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

Subcutaneous use.

Primary vaccination

Sheep from 2 months of age:

Administer two doses of 2 mL subcutaneously 3 weeks apart.

Cattle from 2 month of age:

Administer two doses of 4 mL subcutaneously 3weeks 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 are expected.

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. Therefore, the vaccine should be used in accordance with the benefit/risk assessment carried out by the responsible veterinarian.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : Sheep: QI04AA02, cattle: QI02AA08

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 products 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-authorised product.
Marketed by CZ Vaccines S.A.U.
Allowance for emergency use according to Schedule 4 of the Veterinary Medicine Regulations 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.