

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARDBOARD BOX (52 mL, 100 mL and 252 mL)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

BLUEVAC-3 suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each mL contains:

Bluetongue virus (BTV), serotype 3, strain BTV-3/NET2023, inactivated  $10^{6.5}$  CCID<sub>50</sub>  
\*

\* CCID<sub>50</sub>: 50% cell culture infective dose equivalent to titre prior inactivation

**3. PACKAGE SIZE**

52 mL  
100 mL  
252 mL

**4. TARGET SPECIES**

Sheep and cattle

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Subcutaneous use.

**7. WITHDRAWAL PERIODS**

Withdrawal period: zero days

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 10 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.  
Do not freeze.  
Protect from light.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

CZ Vaccines S.A.U.

**14. MARKETING AUTHORISATION NUMBER**

Vm 30824/5002

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle of 52 mL,  
100 mL and 252 mL}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

BLUEVAC-3 suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each mL contains:

Bluetongue virus (BTV), serotype 3, strain BTV-3/NET2023, inactivated  $10^{6.5}$  CCID<sub>50</sub>  
\*

\* CCID<sub>50</sub>: 50% cell culture infective dose equivalent to titre prior inactivation

**3. TARGET SPECIES**

Sheep and cattle.

**4. ROUTES OF ADMINISTRATION**

SC. Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal periods: Zero days.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 10 hours.

**7. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Do not freeze.

Protect from light.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

CZ Vaccines S.A.U.

**9. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

BLUEVAC-3 suspension for injection for sheep and cattle.

**2. Composition**

Each mL contains:

**Active substance:**

Bluetongue virus (BTV), serotype 3, strain BTV-3/NET2023, inactivated  $10^{6.5}$  CCID<sub>50</sub>  
\*

\* CCID<sub>50</sub>: 50% cell culture infective dose equivalent to titre prior inactivation.

**Adjuvants:**

Aluminium hydroxide .....6 mg  
Purified saponin (Quil A) .....0.05 mg

**Excipients:**

Thiomersal .....0.1 mg

White or pinkish-white suspension.

**3. Target species**

Sheep and cattle.

**4. Indications for use**

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.

## **5. Contraindications**

None.

## **6. Special warnings**

### 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.

### 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.

### 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.

### 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:

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

### Special restrictions for use and special conditions for use:

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.

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

## 7. Adverse events

### Sheep:

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

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

<sup>2</sup>Painless, diameter up to 4 cm, recedes within 14 days.

<sup>3</sup>Up to 1 °C, for up to 72 hours.

### Cattle:

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

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

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

<sup>3</sup>Up to 1 °C, for up to 24 hours.

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 can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## **8. Dosage for each species, routes and method of administration**

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

## **9. Advice on correct administration**

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

## **10. Withdrawal periods**

Zero days.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C)

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton after Exp. The expiry date refers to the last day of that 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**

Vm 30824/5002

#### 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.

### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release:

CZ Vaccines S.A.U.  
A Relva s/n – Torneiros  
36410 O Porriño  
Pontevedra  
Spain

Local representatives and contact details to report suspected adverse reactions:

Ceva Animal Health Limited  
Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, HP10 0HH High Wycombe,  
The United Kingdom  
Tel: + 44 1628 334 056

**17. Other information**

POM-V

*Gavin Hall*

Approved: 24 April 2025