**ANNEX I**

**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..... $10^{6.5}$ $CCID_{50}$ *

* $CCID_{50}$: 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 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<br>(>1 animal / 10 animals treated): | Injection site swelling[1]<br>Injection site nodule[2] |
| Common<br>(1 to 10 animals / 100 animals treated): | Elevated temperature[3] |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Loss of appetite<br>Hypersensitivity reaction |

[1]Painless, diameter up to 4 cm, for up to 9 days, transforms into a nodule.
[2]Painless, diameter up to 4 cm, recedes within 14 days.
[3]Up to 1 ºC, for up to 72 hours.

Cattle:

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

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

[2]Painless, diameter 0.5 to 9 cm, recedes in 25% of animals within 21 days.
[3]Up to 1 ºC, 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 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

CZ Vaccines S.A.U.

## 7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/331/001-003

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 20/02/2025.

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

{MM/YYYY}

**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 PRODUCTS

Veterinary medicinal product subject to prescription.

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

# ANNEX II

# OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

## OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

## SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES

This being an approval under exceptional circumstances and pursuant to Article 25 of Regulation (EU) 2019/6, the MAH shall conduct, within the stated timeframe, the following measures:

| Description | Due date |
|---|---|
| The results of real time stability studies for the vaccine, up to 27 months, should be provided to confirm the 2-year shelf-life claim. Any out of specification detected should be communicated immediately to the European Medicines Agency. | April 2027 |
| The results of stability studies for the active substance (BTV-3 antigen), up to 24 months, should be provided to confirm the shelf-life claim. Any out of specification detected should be communicated immediately to the European Medicines Agency. | November 2026 |
| In addition to the legal requirements applicable to reporting of adverse reactions, the applicant is required to specifically monitor and evaluate the following suspected adverse events: effects on milk production in cattle. | September 2025 |
| A study on duration of immunity in sheep and cattle should be conducted and data should be provided as soon as available. | January 2027 |

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**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..... $10^{6.5}$ $CCID_{50}$ *

* $CCID_{50}$: 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 NUMBERS

EU/2/24/331/001
EU/2/24/331/002
EU/2/24/331/003

## 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..... $10^{6.5}$ $CCID_{50}$ *

* $CCID_{50}$: 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 period: 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}

**B. 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..... $10^{6.5}$ $CCID_{50}$ *

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

**Adjuvants:**

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

**Excipients:**

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[1]<br>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<br>Hypersensitivity reaction |

[1]Painless, diameter up to 4 cm, for up to 9 days, transforms into a nodule.
[2]Painless, diameter up to 4 cm, recedes within 14 days.
[3]Up to 1 ºC, for up to 72 hours.

Cattle:

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

[1]Painless, diameter up to 9 cm, for up to 6 days, transforms into a nodule.
[2]Painless, diameter 0.5 to 9 cm, recedes in 25% of animals within 21 days.
[3]Up to 1 ºC, 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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## 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 and transport refrigerated (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

EU/2/24/331/001-003

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. Date on which the package leaflet was last revised

{MM/YYYY}

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

## 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:

**België/Belgique/Belgien**
Kernfarm B.V.
De Corridor 14D 3621 ZB
Breukelen
Nederland/Pays-Bas/Niederlande
Tél: +31 (0) 346 785 139

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spanje/Espagne/Spanien
Tél: +34 986 330 400

**Magyarország**
Ceva-Phylaxia Zrt.
Szallas Utca 5, 1107
Budapest X
Magyarország
Tel.: +36 305731284

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spanyolország
Tel: +34 986 330 400

**Deutschland**
Ceva Tiergesundheit GmbH
Kanzlerstrasse 4 -40472
Düsseldorf
Deutschland
Tel: +49 1727610543

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spanien
Tel: +34 986 330 400

**Česká republika**
Ceva Animal Health Slovakia S.r.o.
Prievozska 5434/6a, 821 09
Bratislava
Slovenská republika
Tel: +421 918975177

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Španělsko
Tel: +34 986 330 400

**Danmark**
Ceva Animal Health A/S
Porschevej 12 – 7100
Vejle
Danmark
Tlf: +45 23848860

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spanien
Tel: +34 986 330 400

**Nederland**
Kernfarm B.V.
De Corridor 14D 3621 ZB
Breukelen
Nederland
Tel: +31 (0) 346 785 139

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spanje
Tel: +34 986 330 400

**Österreich**
Ceva Tiergesundheit GmbH
Kanzlerstrasse 4 -40472
Düsseldorf
Deutschland
Tel: +49 1727610543

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spanien
Tel: +34 986 330 400

**Polska**
Ceva Animal Health Polska Sp. Z o.o, Ul.
Stefana Okrzei Nr1a, 03-715
Warsaw
Polska
Tel.: +48 604267700

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Hiszpania
Tel: +34 986 330 400

**Portugal**
Vetia Animal Health, S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Espanha
Tel: +34 986 330 400

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Espanha
Tel: +34 986 330 400

**España**
Vetia Animal Health, S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
España
Tel: +34 986 330 400

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
España
Tel: +34 986 330 400

**France**
Melchior Santé Animale S.A.S
5 rue Victor Hugo, 69002
Lyon
France
Tél : +33 6 18 15 03 91

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Espagne
Tél: +34 986 330 400

**Slovenská republika**
Ceva Animal Health Slovakia S.r.o.
Prievozska 5434/6a, 821 09
Bratislava
Slovenská republika
Tel: +421 918975177

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Španielsko
Tel: +34 986 330 400

**Italia**
Fatro S.p.A.
Via Emilia, 285
40064 Ozzano dell`Emilia (BO)
Italia
Tel: +39 051 6512711

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spagna
Tel: +34 986 330 400

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

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain
Tel: +34 986 330 400

**Lietuva, Република България, Luxembourg/Luxemburg**, **Malta, Eesti, Norge, Ελλάδα, Hrvatska**, **România, Ireland, Slovenija**, **Ísland, Suomi/Finland**, **Κύπρος, Sverige, Latvija**
CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain
Tel: +34 986 330 400