ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC BTV suspension for injection for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains:

Active substances:
Inactivated bluetongue virus (BTV)

A maximum of two (cattle) or three (sheep) of the following inactivated bluetongue virus serotypes:

Bluetongue virus, serotype 1, strain ALG2006/01 E1, inactivated	≥ 9.06 mcg/ml
Bluetongue virus, serotype 4, strain SPA-1/2004, inactivated	≥ 22.06 mcg/ml
Bluetongue virus, serotype 8, strain BEL2006/01, inactivated	≥ 245.67 mcg/ml

The type of strain(s) included in the final product will be selected based on the epidemiological situation at the time of manufacturing and will be stated on the label.

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 prevent the viraemia* caused by bluetongue virus serotype 1 and/or 4 and/or 8 and to reduce clinical signs caused by bluetongue virus serotype 8 (combination of maximum 3 serotypes)

* Below the level of detection by the validated RT-PCR method at 1 log10 $TCID_{50}$/ml for serotypes 8 and 4, and 1.3 log10 $TCID_{50}$/ml for serotype 1.

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

Duration of immunity: 1 year after completion of the primary vaccination scheme.

Cattle
For active immunisation of cattle to prevent viraemia* caused by bluetongue virus serotype 1 and/or 4 and/or 8 (combination of maximum 2 serotypes).

* Below the level of detection by the validated RT-PCR method at 1 log10 $TCID_{50}$/ml for serotypes 8 and 4, and 1.3 log10 $TCID_{50}$/ml for serotype 1.

Onset of immunity: BTV, serotype 1: 4 weeks after completion of the primary vaccination scheme
BTV, serotype 4: 3 weeks after completion of the primary vaccination scheme
BTV, serotype 8: 31 days after completion of the primary vaccination scheme

Duration of immunity: 1 year after completion of the primary vaccination scheme.

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.

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	Elevated temperature[2]

(1 to 10 animals / 100 animals treated):	
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Loss of appetite Hypersensitivity reaction

[1]Painless, diameter 0.5 to 3 cm, for up to 14 days, although some can persist after that time.
[2] Up to 1 ºC, for 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):	Elevated temperature[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Loss of appetite Hypersensitivity reaction

[1]Painless, diameter 0.5 to 5 cm, for up to 21 days, although some can persist after that time.
[2]Up to 1 ºC, for 24 to 72 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 its local representative 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:
There is no negative impact on the milk yield using the vaccine in lactating ewes and cows.

Fertility:
The safety and efficacy of the vaccine 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.

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

Primary vaccination

Sheep:

Sheep from 2.5 months of age:
Administer two doses of 2 ml subcutaneously 3 weeks apart.
For monovalent vaccines containing bluetongue virus serotype 1 or serotype 4 administer one dose of 2 ml subcutaneously. For bivalent vaccines containing bluetongue virus serotype 1 and serotype 4 administer one dose of 2 ml subcutaneously.

Cattle:

Cattle from 2 months of age:
Administer two doses of 4 ml subcutaneously 3-4 weeks apart.

Revaccination

An annual revaccination is recommended.

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

BLUEVAC BTV stimulates active immunity of sheep and cattle against bluetongue virus serotype(s) related to those contained in the vaccine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life formulation with Bluetongue virus serotype 1: 18 months.
Shelf life formulation with Bluetongue virus serotype 4 or 8: 2 years.

Shelf life after first opening the immediate packaging: 10 hours

5.3 Special precautions for storage

Store and transport refrigerated (2 ºC – 8 ºC).
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/2/11/122/001-021

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 14/04/2011

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

04/2026

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

None.

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 BTV suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of vaccine contains:

BTV-1 antigen ≥ 9.06 mcg
BTV-4 antigen ≥ 22.06 mcg
BTV-8 antigen ≥ 245.67 mcg

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/2/11/122/001 bottle of 52 ml
EU/2/11/122/002 bottle of 100 ml
EU/2/11/122/003 bottle of 252 ml
EU/2/11/122/004 bottle of 52 ml
EU/2/11/122/005 bottle of 100 ml
EU/2/11/122/006 bottle of 252 ml
EU/2/11/122/007 bottle of 52 ml
EU/2/11/122/008 bottle of 100 ml
EU/2/11/122/009 bottle of 252 ml
EU/2/11/122/010 bottle of 52 ml
EU/2/11/122/011 bottle of 100 ml
EU/2/11/122/012 bottle of 252 ml
EU/2/11/122/013 bottle of 52 ml
EU/2/11/122/014 bottle of 100 ml
EU/2/11/122/015 bottle of 252 ml
EU/2/11/122/016 bottle of 52 ml
EU/2/11/122/017 bottle of 100 ml
EU/2/11/122/018 bottle of 252 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (52 ml, 100 ml and 252 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC BTV suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of vaccine contains:

BTV-1 antigen ≥ 9.06 mcg
BTV-4 antigen ≥ 22.06 mcg
BTV-8 antigen ≥ 245.67 mcg

3. PACKAGE SIZE

52 ml
100 ml
252 ml

4. TARGET SPECIES

Sheep

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/2/11/122/019 bottle of 52 ml
EU/2/11/122/020 bottle of 100 ml
EU/2/11/122/021 bottle of 252 ml

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 BTV suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

BTV-1 antigen ≥ 9.06 mcg/ml
BTV-4 antigen ≥ 22.06 mcg /ml
BTV-8 antigen ≥ 245.67 mcg/ml

3. TARGET SPECIES

Sheep and cattle.

4. ROUTES OF ADMINISTRATION

s.c.
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 IMMEDIATE PACKAGE

Bottle of 52 ml, 100 ml and 252 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC BTV suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

BTV-1 antigen ≥ 9.06 mcg/ml
BTV-4 antigen ≥ 22.06 mcg /ml
BTV-8 antigen ≥ 245.67 mcg/ml

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

s.c.
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}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

BLUEVAC BTV suspension for injection for cattle and sheep

2. Composition

Each ml of vaccine contains:

Active substances:

Inactivated bluetongue virus (BTV)

A maximum of two (cattle) or three (sheep) of the following inactivated bluetongue virus serotypes:

Bluetongue virus, serotype 1, strain ALG2006/01 E1, inactivated	≥ 9.06 mcg/ml
Bluetongue virus, serotype 4, strain SPA-1/2004, inactivated	≥ 22.06 mcg/ml
Bluetongue virus, serotype 8, strain BEL2006/01, inactivated	≥ 245.67 mcg/ml

The type of strain(s) included in the final product will be selected based on the epidemiological situation at the time of manufacturing and will be stated on the label.

Adjuvants:

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

Excipient:

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 prevent the viraemia* caused by bluetongue virus serotype 1 and/or 4 and/or 8 and to reduce clinical signs caused by bluetongue virus serotype 8 (combination of maximum 3 serotypes).

* Below the level of detection by the validated RT-PCR method at 1 log10 $TCID_{50}$/ml for serotypes 8 and 4, and 1.3 log10 $TCID_{50}$/ml for serotype 1

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

Duration of immunity: 1 year after completion of the primary vaccination scheme.

Cattle

For active immunisation of cattle to prevent viraemia* caused by bluetongue virus serotype 1 and/or 4 and/or 8 (combination of maximum 2 serotypes).

* Below the level of detection by the validated RT-PCR method at 1 log10 $TCID_{50}$/ml for serotypes 8 and 4, and 1.3 log10 $TCID_{50}$/ml for serotype 1.

Onset of immunity: BTV, serotype 1: 4 weeks after completion of the primary vaccination scheme
BTV, serotype 4: 3 weeks after completion of the primary vaccination scheme
BTV, serotype 8: 31 days after completion of the primary vaccination scheme

Duration of immunity: 1 year after completion of the primary vaccination scheme.

5. Contraindications

None.

6. Special warnings

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.

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:
There is no negative impact on the milk yield using the vaccine in lactating ewes and cows.

Fertility:
The safety and efficacy of the vaccine 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).

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

[1]Painless, diameter 0.5 to 3 cm, for up to 14 days, although some can persist after that time.
[2] Up to 1 ºC, for 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):
Elevated temperature[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Loss of appetite Hypersensitivity reaction

[1]Painless, diameter 0.5 to 5 cm, for up to 21 days, although some can persist after that time.
[2]Up to 1 ºC, for 24 to 72 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 its local representative 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:

Sheep from 2.5 months of age:
Administer two doses of 2 ml subcutaneously 3 weeks apart.
For monovalent vaccines containing bluetongue virus serotype 1 or serotype 4 administer one dose of 2 ml subcutaneously. For bivalent vaccines containing bluetongue virus serotype 1 and serotype 4 administer one dose of 2 ml subcutaneously.

Cattle:

Cattle from 2 months of age:
Administer two doses of 4 ml subcutaneously 3-4 weeks apart.

Revaccination

An annual revaccination is recommended.

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/2/11/122/001-021

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

04/2026

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 and contact details to report suspected adverse events:
CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain
Tel: +34 986 330 400

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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

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

Ελλάδα
VIRBAC HELLAS SINGLE MEMBER SA
13 th Km National Road Athens Lamia
14452, Metamorfosi
Greece
Tel: +30 210 62 19 520

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

Italia
Fatro S.p.A. – Veterinary Pharmaceutical Industry
Via Emilia, 285
40064 Ozzano dell`Emilia (BO)
Italy
Tel: +39 051 6512711

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

Magyarország
Ceva-Phylaxia Zrt.
Szállás u. 5.
1107 Budapest
Magyarország
Tel.: +800 35 22 11 51

Danmark
Ceva Animal Health A/S
Porschevej 12
7100 Vejle
Danmark
Tlf.: +800 35 22 11 51

Polska
Ceva Animal Health Polska Sp. z o.o.
ul. Stefana Okrzei 1A
03-715 Warszawa
Polska
Tel.: +800 35 22 11 51

Sverige
Ceva Animal Health AB
Annedalsvägen 9
227 64 Lund
Sverige
Tel: +800 35 22 11 51

Република България
"АСКЛЕП - ФАРМА" ООД
ж.к. Люлин 7, бл. 711А, магазин 3
BG София, 1324
Тел: +359888837190