

**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 of the following inactivated bluetongue virus serotypes:

Inactivated bluetongue virus, serotype 1 (BTV-1), strain BTV-1/ALG/2006/01	$\geq 9.06 \mu\text{g/ml}$
Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004	$\geq 22.06 \mu\text{g/ml}$
Inactivated bluetongue virus, serotype 8 (BTV-8), strain BTV8/BEL/2006/01	$\geq 245.67 \mu\text{g/ml}$

### Adjuvants:

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

### Excipients:

Thiomersal	0.1 mg
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For the full list of excipients, see section 6.1.

The type of strain(s) (two strains at most) 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.

## 3. PHARMACEUTICAL FORM

Suspension for injection.

White or pinkish-white suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Sheep and cattle.

### 4.2 Indications for use, specifying the 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 2 serotypes)

\* Below the level of detection by the validated RT-PCR method at  $1 \log_{10} \text{TCID}_{50}/\text{ml}$  for serotypes 8 and 4, and  $1.3 \log_{10} \text{TCID}_{50}/\text{ml}$  for serotype 1.

Onset of immunity: 21 days 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 log<sub>10</sub> TCID<sub>50</sub>/ml for serotypes 8 and 4, and 1.3 log<sub>10</sub> TCID<sub>50</sub>/ml for serotype 1.

Onset of immunity: BTV, serotype 1: 28 days after completion of the primary vaccination scheme  
BTV, serotype 4: 21 days 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.

### **4.3 Contraindications**

None.

### **4.4 Special warnings for each target species**

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 sheep and cattle.

### **4.5 Special precautions for use**

#### Special precautions for use in animals

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.

### **4.6 Adverse reactions (frequency and seriousness)**

#### Sheep:

A transient increase in rectal temperature not exceeding 1°C is common. It lasts not longer than 24 to 72 hours.

Temporary local reactions at the injection site in the format of a normally painless nodule of 0.5 to 3 cm which decreases progressively over time occur very common.

Most local reactions disappear before 14 days, although some can persist after that time.

In very rare cases, loss of appetite can occur. Hypersensitivity reactions are very rarely observed.

#### Cattle:

A transient increase in rectal temperature is rare.

Temporary local reactions at the injection site in the format of a normally painless nodule of 0.5 to 5 cm which decreases progressively over time occur very common.

Most local reactions disappear before 21 days, although some can persist after that time.

In very rare cases, loss of appetite can occur. Hypersensitivity reactions are very rarely observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### **4.7 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 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).

#### **4.8 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.

#### **4.9 Amounts to be administered and administration route**

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 vaccine 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.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

After the administration of a double dose, no adverse reactions other than those described in section 4.6 were observed.

#### **4.11 Withdrawal period**

Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Inactivated bluetongue virus vaccines for sheep.  
ATC vet code: QI04AA02.

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

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Aluminium hydroxide  
Purified saponin (Quil A)  
Thiomersal  
Phosphate buffered saline (sodium chloride, disodium phosphate and potassium phosphate, water for injections)

#### **6.2 Major incompatibilities**

Do not mix with any other veterinary medicinal products.

#### **6.3 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

#### **6.4. Special precautions for storage**

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

#### **6.5 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.

## **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

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

## **8. MARKETING AUTHORISATION NUMBER(S)**

EU/2/11/122/001  
EU/2/11/122/002  
EU/2/11/122/003  
EU/2/11/122/004  
EU/2/11/122/005  
EU/2/11/122/006  
EU/2/11/122/007  
EU/2/11/122/008  
EU/2/11/122/009  
EU/2/11/122/010  
EU/2/11/122/011  
EU/2/11/122/012  
EU/2/11/122/013  
EU/2/11/122/014  
EU/2/11/122/015  
EU/2/11/122/016  
EU/2/11/122/017  
EU/2/11/122/018

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 14/04/2011  
Date of last renewal: 15/03/2016

## **10. DATE OF REVISION OF THE TEXT**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

## **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Any person intending to manufacture, import, possess, sell, supply and use of BLUEVAC BTV 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.

## **ANNEX II**

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**
- D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND  
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substance

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

Name and address of the manufacturer responsible for batch release

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

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

- a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.
- b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

**C. STATEMENT OF THE MRLs**

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

**D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING  
AUTHORISATION**

The current annual reporting cycle for periodic safety update reports (PSURs) should be maintained.



**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 for cattle and sheep

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml of vaccine contains:

BTV1 antigen  $\geq 9.06 \mu\text{g}$

BTV4 antigen  $\geq 22.06 \mu\text{g}$

BTV8 antigen  $\geq 245.67 \mu\text{g}$

**3. PHARMACEUTICAL FORM**

Suspension for injection.

**4. PACKAGE SIZE**

52ml

100 ml

252 ml

**5. TARGET SPECIES**

Sheep and cattle.

**6. INDICATION(S)****7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Subcutaneous use.

Shake well before use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period: zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Once opened, use within 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated.

Do not freeze.

Protect from light.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

CZ Vaccines S.A.U.

36410 O Porriño – Spain

**16. MARKETING AUTHORISATION NUMBER(S)**

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

<b>17. MANUFACTURER'S BATCH NUMBER</b>
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Batch: {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 for cattle and sheep

**2. STATEMENT OF ACTIVE SUBSTANCES**

BTV1 antigen  $\geq 9.06 \mu\text{g/ml}$

BTV4 antigen  $\geq 22.06 \mu\text{g /ml}$

BTV8 antigen  $\geq 245.67 \mu\text{g/ml}$

**3. PHARMACEUTICAL FORM**

Suspension for injection.

**4. PACKAGE SIZE**

52 ml

100 ml

252 ml

**5. TARGET SPECIES**

Sheep and cattle.

**6. INDICATION(S)****7. METHOD AND ROUTE(S) OF ADMINISTRATION**

SC

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period: zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Once opened, use within 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated.

Do not freeze.

Protect from light.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

CZ Vaccines S.A.U.

36410 O Porriño – Spain

**16. MARKETING AUTHORISATION NUMBER(S)**

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

<b>17. MANUFACTURER'S BATCH NUMBER</b>
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Batch: {number}



## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**BLUEVAC BTV Suspension for injection for cattle and sheep**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:

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

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

BLUEVAC BTV Suspension for injection for cattle and sheep

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each ml of vaccine contains:

**Active substances:**

Inactivated bluetongue virus (BTV)

A maximum of two of the following inactivated bluetongue virus serotypes:

Inactivated bluetongue virus, serotype 1 (BTV-1), strain BTV-1/ALG/2006/01	≥ 9.06 µg/ml
Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004	≥ 22.06 µg/ml
Inactivated bluetongue virus, serotype 8 (BTV-8), strain BTV8/BEL/2006/01	≥ 245.67 µg/ml

**Adjuvants:**

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

**Excipient:**

Thiomersal	0.1 mg
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The type of strain(s) (two strains at most) 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.

White or pinkish-white suspension.

**4. INDICATION(S)**

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 2 serotypes).

\* Below the level of detection by the validated RT-PCR method at 1 log<sub>10</sub> TCID<sub>50</sub>/ml for serotypes 8 and 4, and 1.3 log<sub>10</sub> TCID<sub>50</sub>/ml for serotype 1

Onset of immunity: 21 days 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 log<sub>10</sub> TCID<sub>50</sub>/ml for serotypes 8 and 4, and 1.3 log<sub>10</sub> TCID<sub>50</sub>/ml for serotype 1.

Onset of immunity: BTV, serotype 1: 28 days after completion of the primary vaccination scheme  
BTV, serotype 4: 21 days 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. ADVERSE REACTIONS**

### Sheep:

A transient increase in rectal temperature not exceeding 1°C is common. It lasts not longer than 24 to 72 hours.

Temporary local reactions at the injection site in the format of a normally painless nodule of 0.5 to 3 cm which decreases progressively over time occur very common.

Most local reactions disappear before 14 days, although some can persist after that time.

In very rare cases, loss of appetite can occur. Hypersensitivity reactions are very rarely observed.

### Cattle:

A transient increase in rectal temperature is rare.

Temporary local reactions at the injection site in the format of a normally painless nodule of 0.5 to 5 cm which decreases progressively over time occur very common.

Most local reactions disappear before 21 days, although some can persist after that time.

In very rare cases, loss of appetite can occur. Hypersensitivity reactions are very rarely observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

## **7. TARGET SPECIES**

Sheep and cattle.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 vaccine 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 PERIOD(S)**

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.

Shelf life after first opening the container: 10 hours.

## **12. SPECIAL WARNING(S)**

Special warnings for each target species

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 sheep and cattle.

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 (symptoms, emergency procedures, antidotes):

After the administration of a double dose, no adverse reactions other than those described in section 6 were observed.

Incompatibilities:

Do not mix with any other veterinary medicinal products.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Detailed information on this veterinary medicinal is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

**15. OTHER INFORMATION**

Pharmacotherapeutic group: Bluetongue virus vaccines, inactivated.  
ATC vet code: QI04AA02

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

Pack sizes:

Cardboard box of 1 bottle containing 52 ml

Cardboard box of 1 bottle containing 100 ml

Cardboard box of 1 bottle containing 252ml

Not all pack sizes may be marketed.

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

**Република България**

"АСКЛЕП - ФАРМА" ООД

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BG София, 1324

Тел: +359888837190

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A Relva s/n – Torneiros

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A Relva s/n – Torneiros

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36410 O Porriño

Pontevedra

Spanje

Tel: +34 986330400

**España**

Vetia Animal Health, S.A.U.

A Relva s/n – Torneiros

36410 O Porriño

Pontevedra

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CZ Vaccines S.A.U.

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36410 O Porriño  
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Tel: +34 986330400

**Ελλάδα**

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