

**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 AND OTHER SUBSTANCES**

Each ml of vaccine contains:

BTV1 antigen  $\geq 22.60 \mu\text{g}$

BTV4 antigen  $\geq 2.55 \mu\text{g}$

BTV8 antigen  $\geq 55.80 \mu\text{g}$

**3. PACKAGE SIZE**

52 ml

100 ml

252 ml

**4. TARGET SPECIES**

Sheep and cattle.

**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

Subcutaneous use.

Shake well before use.

**7. WITHDRAWAL PERIODS**

**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**

## **14. MARKETING AUTHORISATION NUMBERS**

Vm 30824/5001

## **15. BATCH NUMBER**

Lot {number}

## **16. SPECIAL WARNING(S), IF NECESSARY**

## **17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: Read package leaflet

## **18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

POM-V

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle of 100 ml  
and 252 ml }**

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

BLUEVAC BTV Suspension for injection.

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

BTV1 antigen  $\geq 22.60 \mu\text{g/ml}$

BTV4 antigen  $\geq 2.55 \mu\text{g /ml}$

BTV8 antigen  $\geq 55.80 \mu\text{g/ml}$

**3. TARGET SPECIES**

Sheep and cattle.

**4. ROUTES OF ADMINISTRATION**

SC

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

**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**

**9. BATCH NUMBER**

Lot {number}

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

**11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: Read package leaflet.

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

For animal treatment only.

POM-V

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING**  
**UNITS {Bottle of 52 ml}**

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

Bluevac BTV

**2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

BTV1 antigen  $\geq 22.60 \mu\text{g/ml}$

BTV4 antigen  $\geq 2.55 \mu\text{g/ml}$

BTV8 antigen  $\geq 55.80 \mu\text{g/ml}$

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

EXP {mm/yyyy}

Once opened, use within 10 hours.

**5. ROUTE(S) OF ADMINISTRATION**

SC

**6. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**PARTICULARS TO APPEAR ON THE 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)

One of the following inactivated bluetongue virus serotypes:

Inactivated bluetongue virus, serotype 1 (BTV-1), strain BTV-1/ALG/2006/01	≥ 22.60 µg/ml
Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004	≥ 2.55 µg/ml
Inactivated bluetongue virus, serotype 8 (BTV-8), strain BTV8/BEL/2006/01	≥ 55.80 µg/ml

**Adjuvants:**

Aluminium hydroxide            6 mg

Purified saponin (Quil A)    0.05 mg

**Excipient:**

Thiomersal                        0.1 mg

The type of strain 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.

**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 or 4 or 8) and to reduce clinical signs caused by bluetongue virus serotype 8.

\* 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 or 4 or 8.

\* 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. SPECIAL WARNINGS**

### 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 7 were observed.

Incompatibilities:

Do not mix with any other veterinary medicinal products.

## 7. ADVERSE EVENTS

Sheep:

Very common (>1 animal / 10 animals treated):	Injection site nodule/2605*
Common (1 to 10 animals / 100 animals treated):	Hyperthermia/604**
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction/2241 Appetite loss/997

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

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

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site nodule/2605*
Rare (1 to 10 animals / 10,000 animals treated):	Hyperthermia/604**
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction/2241 Appetite loss/997

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

\*\*A transient increase in rectal temperature.

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.

## **8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION**

Subcutaneous use.

### **Primary vaccination**

Sheep:

#### Sheep from 2.5 months of age:

For monovalent vaccine containing bluetongue virus serotype 1 or serotype 4 administer one dose of 2 ml subcutaneously.

For monovalent vaccine containing bluetongue virus serotype 8 administer two doses of 2 ml subcutaneously 3 weeks apart.

Cattle:

#### Cattle from 2 months of age:

Administer two doses of 4 ml subcutaneously with a 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.

Shelf life after first opening the container: 10 hours.

## **12. SPECIAL PRECAUTIONS FOR DISPOSAL**

Ask your veterinary surgeon how to dispose of medicines no longer required.

## **13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 30824/5001

### 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.

## **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 and contact details to report suspected adverse reactions:

CZ Vaccines S.A.U.  
A Relva s/n - Torneiros  
36410 O Porriño  
Pontevedra  
Spain  
Tel: +34 986 33 04 00

## **17. 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.

### **POM-V**

For animal treatment only.

*Gavin Hall*  
Approved: 17 October 2025