

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)

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

Excipients:

Thiomersal 0.1 mg

For the full list of excipients, see section 6.1.

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.

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 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 log₁₀ TCID₅₀/ml for serotypes 8 and 4, and 1.3 log₁₀ TCID₅₀/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 log₁₀ TCID₅₀/ml for serotypes 8 and 4, and 1.3 log₁₀ TCID₅₀/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:

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 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 also section 16 of the package leaflet for contact details.

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 Amount(s) 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:

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 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(s)

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 product.

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

Vm 30824/5001

9. DATE OF FIRST AUTHORISATION

14 April 2011

10. DATE OF REVISION OF THE TEXT

October 2025

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant competent authority on the current vaccination policies, as these activities may be prohibited in a country on the whole or part of its territory pursuant to national legislation.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall
Approved: 17 October 2025