# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvazul BTV suspension for injection for sheep and cattle

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substances*:**

Inactivated bluetongue virus (BTV) RP** ≥ 1

* Maximum of two different inactivated bluetongue virus serotypes:
Inactivated bluetongue virus, serotype 1 (BTV-1), strain ALG2006/01 E1
Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004
Inactivated bluetongue virus, serotype 8 (BTV-8), strain BEL2006/01

** Relative potency measured by ELISA in relation to a reference vaccine whose efficacy has been demonstrated by challenge in the target species.

The number and type(s) of strains included in the final product will be adapted to the current epidemiological situation at the time of formulation of the final product and will be shown on the label.

**Adjuvants:**

| | |
|---|---|
| Aluminium hydroxide (Al3+) | 2.08 mg |
| Semi-purified saponin from *Quillaja saponaria* | 0.2 mg |

**Excipient:**

| | |
|---|---|
| Thiomersal | 0.1 mg |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Suspension for injection.
Pinkish-white suspension easily homogenised by shaking.

## 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 viraemia* and reduce clinical signs and lesions caused by bluetongue virus serotypes 1 and/or 8 and/or to reduce viraemia* and clinical signs and lesions caused by bluetongue virus serotype 4 (combination of maximum 2 serotypes).

*Below the level of detection by the validated RT-PCR method at 1.32 $\log_{10}$ $TCID_{50}$/ml

Onset of immunity: 39 days after completion of the primary vaccination scheme.
Duration of immunity: one year after completion of the primary vaccination scheme.

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

*Below the level of detection by the validated RT-PCR method at 1.32 $\log_{10}$ $TCID_{50}$/ml

Onset of immunity: 21 days after completion of the primary vaccination scheme.
Duration of immunity: one year after completion of the primary vaccination scheme.

## 4.3 Contraindications

None.

## 4.4 Special warnings for each target species

Vaccinate healthy animals only.

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.

No information is available on the use of the vaccine in sheep with maternally-derived antibodies.

No information is available on the use of the vaccine containing BTV4 serotype in cattle with maternally-derived antibodies.

## 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.

People with known hypersensitivity to aluminium hydroxide, thiomersal or saponins should avoid contact with the veterinary medicinal product.

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

The development of local reactions is very common at the site of injection after vaccination.

Erythema associated with mild to moderate oedema is very common from 1 to 6 days after the administration.

A painless nodule that may reach up to 3.8 cm diameter in sheep and 7 cm diameter in cattle develops very commonly after 2 to 6 days and diminishes progressively over time.

An abscess may appear on rare occasions.

Most local reactions disappear or become residual (≤ 1 cm) before 70 days in sheep and 30 days in cattle, although residual nodules can persist after that time.

A transient increase in rectal temperature, not exceeding 2.3 °C, during the 48 hours following vaccination, is very common.

The following might be observed on rare occasions in sheep and on very rare occasions in cattle:

- Reproductive system disorders: abortion, perinatal mortality or premature parturition
- Systemic disorders: apathy, recumbency, fever, anorexia or lethargy.

The following might be observed on very rare occasions in sheep and cattle:

- Reduction in milk production
- Neurological disorders: paralysis, ataxia, blindness or incoordination
- Respiratory tract disorders: pulmonary congestion, dyspnoea
- Digestive tract disorders: rumen atony or bloating
- Hypersensitivity reactions: with hypersalivation
- Death.

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.

Lactation:

Can be used during lactation.

Fertility:

The safety and the efficacy of the vaccine have 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 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

Shake well before use.

**Sheep:**

Subcutaneous use.

Administer subcutaneously to sheep from 3 months of age, according to the following scheme:

- Primary vaccination: administer a single 2 ml dose.
- Revaccination: administer one dose of 2 ml after 12 months.

**Cattle:**

Intramuscular use.

Administer intramuscularly to cattle from 2 months of age in naïve animals or from 3 months of age in calves born to immune cattle, according to the following scheme:

- Primary vaccination: administer two doses of 4 ml 3 weeks apart.
- Revaccination: administer one dose of 4 ml after 12 months.

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

After administration of a double dose, no other adverse reactions different to those mentioned in section 4.6 were observed.

### 4.11 Withdrawal period(s)

Zero days.

## 5. IMMUNOLOGICAL PROPERTIES

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

To stimulate active immunity of sheep and cattle against bluetongue virus serotypes 1, 4 and/ or 8 related to those contained in the vaccine (combination of maximum 2 serotypes).

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Aluminium hydroxide
Semi-purified saponin from *Quillaja saponaria*
Thiomersal
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate anhydrous
Sodium chloride
Silicon antifoaming agent
Water for injections

### 6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 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.
Store in the original package.

### 6.5 Nature and composition of immediate packaging

Polypropylene colourless vial containing 80 ml or 200 ml, with a type I bromobutyl rubber stopper, sealed with an aluminium closure.

Package sizes:

Cardboard box with 1 vial containing 80 ml.

Cardboard box with 1 vial containing 200 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

Laboratorios SYVA S.A.
Calle Marqués de la Ensenada, 16
28004 Madrid
Spain

## 8. MARKETING AUTHORISATION NUMBER

Vm 31592/5000

## 9. DATE OF FIRST AUTHORISATION

09 January 2019

## 10. DATE OF REVISION OF THE TEXT

October 2025

## PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, 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.

*Gavin Hall*
Approved: 17 October 2025