PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 vial of 80 ml
Box of 1 vial of 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvazul BTV suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance(s):

Inactivated bluetongue virus, serotype 1 (BTV-1), strain ALG2006/01 E1RP* ≥ 1
Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004 RP* ≥ 1
Inactivated bluetongue virus, serotype 8 (BTV-8), strain BEL2006/01 RP* ≥ 1

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

Adjuvants:

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

Excipient:

Thiomersal	0.1 mg

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

80 ml
200 ml

5. TARGET SPECIES

Sheep and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Sheep: Subcutaneous use.
Cattle: Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.
Store in the original package.

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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31592/5000

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 80 ml
Vial of 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvazul BTV suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance(s):

Inactivated bluetongue virus, serotype 1 (BTV-1), strain ALG2006/01 E1 RP* ≥ 1
Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004 RP* ≥ 1
Inactivated bluetongue virus, serotype 8 (BTV-8), strain BEL2006/01 RP* ≥ 1

* Relative potency compared to a reference vaccine.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

80 ml
200 ml

5. TARGET SPECIES

Sheep and cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Sheep: Subcutaneous use.
Cattle: Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Shake well before use.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Do not freeze.
Store and transport refrigerated.
Protect from light.
Store in the original package.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31592/5000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET:
Syvazul BTV suspension for injection for sheep and cattle

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

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

LABORATORIOS SYVA, S.A. Parque Tecnológico de León C/ Nicostrato Vela M15-M16
24009 LEÓN
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvazul BTV suspension for injection for sheep and cattle

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

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

Pinkish-white suspension for injection easily homogenised by shaking.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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 (≤ 1cm) 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).

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Protect from light.
Store in the original package.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last date of that month.

Shelf life after first opening the immediate packaging: 10 hours.

12. SPECIAL WARNING(S)

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.

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.

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).

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 administration of a double dose, no other adverse reactions different to those mentioned in ‘ADVERSE REACTIONS’ were observed.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

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

Medicines should not be disposed of via wastewater or household waste.

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

14. 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.

15. OTHER INFORMATION

Pack sizes:

Cardboard box with 1 vial containing 80 ml.
Cardboard box with 1 vial containing 200 ml.

Not all pack sizes may be marketed.

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.

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

Gavin Hall
Approved: 17 October 2025