SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvazul BTV 3 suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Bluetongue virus, serotype 3 (BTV-3), strain BTV-3/NET2023, inactivated $\geq 10^{6.9}$ $CCID_{50}$*

* $CCID_{50}$: 50 % cell culture infective dose, determined before inactivation

Adjuvants:

Aluminium hydroxide (Al^{3+})	2.08 mg
Purified saponin (Quil-A) from *Quillaja saponaria*	0.2 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Potassium chloride	
Potassium dihydrogen phosphate	
Disodium hydrogen phosphate anhydrous	
Sodium chloride	
Silicon antifoaming agent	
Water for injections	

Pinkish-white suspension easily homogenised by shaking.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and cattle.

3.2 Indications for use for each target species

Sheep:

For active immunization of sheep to reduce viraemia, to prevent mortality and reduce clinical signs and lesions caused by bluetongue serotype 3.

Onset of immunity: 28 days after completion of the primary vaccination scheme.

The duration of immunity has not been established.

Cattle:

For active immunization against bluetongue virus serotype 3.

The onset of immunity and duration of immunity has not been established.

3.3 Contraindications

None.

3.4 Special warnings

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 and cattle with maternally-derived antibodies.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep

Very common (>1 animal / 10 animals treated):	- Injection site reaction*, Injection site erythema [1,] *, Injection site nodule [2,] * - Hyperthermia [3]
Rare (1 to 10 animals / 10,000 animals treated):	- Injection site abscess* - Abortion, perinatal mortality, premature parturition - Apathy, recumbency, fever, anorexia, lethargy
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	- Milk production decrease - Paralysis, ataxia, blindness, incoordination - Pulmonary congestion, dyspnoea - Rumen atony, bloated

	- Hypersensitivity reactions[4] - Death

* Most local reactions disappear or become residual (≤ 1 cm) before 70 days, although residual nodules can persist after that time.
1. Associated with mild to moderate injection site oedema (from 1 to 6 days after administration).
2. Painless, up to 3.8 cm diameter, after 2 to 6 days and diminishes progressively over time.
3. Not exceeding 2.3 °C, during the 48 hours following vaccination.
4. With hypersalivation.

Cattle

Very common (>1 animal / 10 animals treated):	- Injection site reaction*, Injection site erythema [1,] *, Injection site nodule [2,] * - Hyperthermia [3]
Rare (1 to 10 animals / 10,000 animals treated):	- Injection site abscess*
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	- Abortion, perinatal mortality, premature parturition - Apathy, recumbency, fever, anorexia, lethargy - Milk production decrease - Paralysis, ataxia, blindness, incoordination - Pulmonary congestion, dyspnoea - Rumen atony, bloated - Hypersensitivity reactions[4] - Death

* Most local reactions disappear or become residual (≤ 1 cm) before 30 days, although residual nodules can persist after that time.
1. Associated with mild to moderate injection site oedema (from 1 to 6 days after administration)
2. Painless, up to 7 cm diameter, after 2 to 6 days and diminishes progressively over time.
3. Not exceeding 2.3 °C, during the 48 hours following vaccination.
4. With hypersalivation.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and 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).

3.8 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.

3.9 Administration routes and dosage

Shake 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures antidotes)

The safety of an overdose has not been established.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

The veterinary medicinal product has been approved to be used in exceptional circumstances. The efficacy of the vaccine has not been tested in cattle. Therefore, the vaccine should be used according to the benefit/risk assessment by the responsible veterinarian.

Any person intending to manufacture, import, possess, distribute, 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.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AA02

To stimulate active immunity of sheep and cattle against bluetongue virus serotype 3.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Non-authorized product.
Marketed by LABORATORIOS SYVA, S.A.

Allowance for emergency use according to Schedule 4 of the Veterinary Medicine Regulations 2013.
Assessment based on customised requirements for documentation.

7. MARKETING AUTHORISATION NUMBER(S)

Not applicable (see section 6).

8. DATE OF FIRST AUTHORISATION

Not applicable.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

04/09/2024

EXCEPTIONAL CIRCUMSTANCES:

Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.