

B. PACKAGE LEAFLET

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1. Name of the veterinary medicinal product

Syvazul BTV 3 suspension for injection for sheep and cattle

2. Composition

Each ml contains:

Active substance:

Bluetongue virus, serotype 3 (BTV-3), strain BTV-3/NET2023, inactivated $\geq 10^{7.2}$ CCID₅₀*

* CCID₅₀: Infective dose 50 % in culture cell, determined before inactivation

Adjuvants:

Aluminium hydroxide (Al ³⁺)	2.08 mg
Purified saponin (Quil-A) from <i>Quillaja saponaria</i>	0.2 mg

Excipient:

Thiomersal	0.1 mg
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Pinkish-white suspension easily homogenised by shaking.

3. Target species

Sheep and cattle.

4. Indications for use

Sheep:

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

Onset of immunity: 4 weeks after completion of the primary vaccination scheme.
The duration of immunity has not been established.

Cattle:

For active immunisation of cattle to reduce viraemia caused by bluetongue serotype 3.

Onset of immunity: 3 weeks after completion of the primary vaccination scheme.
The duration of immunity has not been established.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

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

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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

The safety of the vaccine has 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:

The safety of an overdose has not been established.

Special restrictions for use and special conditions for use:

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.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Sheep:

Very common (>1 animal / 10 animals treated):
- Injection site reaction*, Injection site erythema ^{1,*} , Injection site oedema ^{1,*} , Injection site nodule ^{2,*} - Elevated temperature ³
Rare (1 to 10 animals / 10,000 animals treated):
- Injection site abscess* - Abortion, perinatal mortality, premature parturition - Apathy, recumbency, 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, hypersalivation ⁴ - 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. Mild to moderate, 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. Hypersalivation may occur with hypersensitivity reactions.

Cattle:

Very common (>1 animal / 10 animals treated):
- Injection site reaction*, Injection site erythema ^{1,*} , Injection site oedema ^{1,*} , Injection site nodule ^{2,*} - Elevated temperature ³
Rare (1 to 10 animals / 10,000 animals treated):
- Injection site abscess* - Milk production decrease - Anorexia
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
- Abortion, perinatal mortality, premature parturition - Apathy, recumbency, lethargy - High somatic cell count - Paralysis, ataxia, blindness, incoordination - Pulmonary congestion, dyspnoea - Rumen atony, bloated, hypersalivation ⁴ - 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. Mild to moderate, 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. Hypersalivation may occur with hypersensitivity reactions.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

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.

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 2 ml 3 weeks apart.

Revaccination:

Not established.

9. Advice on correct administration

Shake well before use.

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.
Store in the original package.

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

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

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist 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

EU/2/24/332/001-002

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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

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
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN

Local representative and contact details to report suspected adverse reactions:

België/Belgique/Belgien

Local representative:

Alivira NV
Kolonel Begaultlaan 1a
B-3012 Leuven
Tel: + 32 16 84 19 79
E-mail: mail@alivira.be

Contact details to report suspected adverse reactions:

Alivira NV
Tel: + 32 16 84 19 79
E-mail: PHV@alivira.be

Република България

Contact details to report suspected adverse reactions:

Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Тел: +34 987 800 800
E-mail: farmacovigilancia@syva.es

Česká republika

Contact details to report suspected adverse reactions:

Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Tel: +34 987 800 800
E-mail: farmacovigilancia@syva.es

Lietuva

Contact details to report suspected adverse reactions:

Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Tel: +34 987 800 800
E-mail: farmacovigilancia@syva.es

Luxembourg/Luxemburg

Local representative:

Alivira NV
Kolonel Begaultlaan 1a
B-3012 Leuven
Tel: + 32 16 84 19 79
E-mail: mail@alivira.be

Contact details to report suspected adverse reactions:

Alivira NV
Tel: + 32 16 84 19 79
E-mail: PHV@alivira.be

Magyarország

Contact details to report suspected adverse reactions:

Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
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Tel: +34 987 800 800
E-mail: farmacovigilancia@syva.es

Danmark

Local representative:
Salfarm Danmark A/S
Nordager 19,
DK-6000 Kolding,
Tlf: +45 75 50 80 80
info@salfarm.com

Contact details to report suspected adverse reactions:
Salfarm Danmark A/S
Nordager 19,
DK-6000 Kolding,
Tlf: +45 75 50 80 80
info@salfarm.com

Deutschland

Local representative:
Virbac Tierarzneimittel GmbH
Rögen 20
DE-23843 Bad Oldesloe
Tel: +494531 805 111

Contact details to report suspected adverse reactions:
Virbac Tierarzneimittel GmbH
Rögen 20 23843 Bad Oldesloe,
GERMANY
Tel: +494 531 / 805 111
E-mail: arzneimittelsicherheit@virbac.de

Eesti

Contact details to report suspected adverse reactions:
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E-mail: farmacovigilancia@syva.es

Malta

Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
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Tel:+34 987 800 800
E-mail: farmacovigilancia@syva.es

Nederland

Local representative:
Alivira NV
Kolonel Begaultlaan 1a
B-3012 Leuven
Tel: + 32 16 84 19 79
E-mail: mail@alivira.be

Contact details to report suspected adverse reactions:
Alivira NV
Tel: + 32 16 84 19 79
E-mail: PHV@alivira.be

Norge

Local representative
Salfarm Scandinavia AS
Fridtjof Nansens Plass 4,
N-0160, Oslo
Tlf: +47 902 97 102
E-mail: norge@salfarm.com

Contact details to report suspected adverse reactions:
Salfarm Scandinavia AS
Fridtjof Nansens Plass 4,
N-0160, Oslo
Tlf: +47 902 97 102
norge@salfarm.com

ΕλλάδαLocal representative

CEVA ΕΛΛΑΣ ΕΠΕ
Εθνάρχου Μακαρίου 34
EL-16341 ΗΛΙΟΥΠΟΛΗ
Τηλ: +302109851200

Contact details to report suspected adverse reactions:

CEVA HELLAS LLC
4 Ethnarchou Makariou street, 16341
Llioupoli
GREECE
Τηλ: 00 800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

EspañaContact details to report suspected adverse reactions:

Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Tel:+34 987 800 800
E-mail: farmacovigilancia@syva.es

FranceLocal representative:

Laboratoires Biové
3 rue de Lorraine
62510 Arques

Contact details to report suspected adverse reactions:

Laboratoires Biové
Tél: + 33 6 46 52 48 06
E-mail: pv@inovet.eu

HrvatskaContact details to report suspected adverse reactions:

Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
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Tel:+34 987 800 800
E-mail: farmacovigilancia@syva.es

ÖsterreichLocal representative

Virbac Österreich GmbH
Hildebrandgasse 27,
A-1180 Wien,
Tel.: +43 1 2183426

Contact details to report suspected adverse reactions:

Virbac Österreich GmbH,
Hildebrandgasse 27, A-1180 Wien,
Tel.: +43 1 2183426
E-mail: pharmacovigilance@virbac.co.at

PolskaContact details to report suspected adverse reactions:

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Calle Nicostrato Vela M15-M16
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Tel:+34 987 800 800
E-mail: farmacovigilancia@syva.es

PortugalLocal representative:

Iapsa portuguesa pecuária, lda
Av. Do Atlântico, nº 16 – 11ª piso- Escritório 12
PT-1990-019 Lisboa

Contact details to report suspected adverse reactions:

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Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
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Tel: +351 219 747 934
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RomâniaContact details to report suspected adverse reactions:

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Ireland

Contact details to report suspected adverse reactions:

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Ísland

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Italia

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Virbac s.r.l.
Via Ettore Bugatti,
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Tel: +39 02 40 92 47 1

Κύπρος

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Slovenija

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Slovenská republika

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Suomi/Finland

Local representative

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Sverige

Local representative

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SE-254 67 Helsingborg
Tel: +46 767 834 810
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Latvija

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United Kingdom (Northern Ireland)

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