ANNEX I

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:

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, inactivated

** 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 (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 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.

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 with maternally-derived antibodies.

No information is available on the use of the vaccine containing BTV4 serotype in 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 either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See 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 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.

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

No reactions other than those described in section 3.6 occurred following the administration of a two-fold overdose.

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

Administered under veterinary control or supervision.

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 serotypes 1, 4 and/or 8 related to those contained in the vaccine (combination of maximum 2 serotypes).

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

LABORATORIOS SYVA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/18/231/001-012

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/01/2019

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

{MM/YYYY}
{DD/MM/YYYY}
{DD month YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 1 vial of 80 ml
Cardboard box of 1 vial of 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvazul BTV suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

[Maximum of two different inactivated bluetongue virus serotypes]

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

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

3. PACKAGE SIZE

80 ml
200 ml

4. TARGET SPECIES

Sheep and cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Sheep: Subcutaneous use.
Cattle: Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp.{mm/yyyy}
Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS SYVA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/18/231/001: (BTV-1) 80 ml
EU/2/18/231/002: (BTV-1) 200 ml
EU/2/18/231/003: (BTV-4) 80 ml
EU/2/18/231/004: (BTV-4) 200 ml
EU/2/18/231/005: (BTV-8) 80 ml
EU/2/18/231/006: (BTV-8) 200 ml
EU/2/18/231/007: (BTV-1, BTV-4) 80 ml
EU/2/18/231/008: (BTV-1, BTV-4) 200 ml
EU/2/18/231/009: (BTV-1, BTV-8) 80 ml
EU/2/18/231/010: (BTV-1, BTV-8) 200 ml
EU/2/18/231/011: (BTV-4, BTV-8) 80 ml
EU/2/18/231/012: (BTV-4, BTV-8) 200 ml

15. BATCH NUMBER

Lot {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.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

[Maximum of two different inactivated bluetongue virus serotypes]

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

* Relative potency compared to a reference vaccine.

3. TARGET SPECIES

Sheep and cattle.

4. ROUTES OF ADMINISTRATION

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

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS SYVA, S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Syvazul BTV suspension for injection for sheep and cattle

2. Composition

Each ml contains:

Active substances*:

Inactivated bluetongue virus (BTV)	RP** ≥ 1

* Maximum of two different inactivated bluetongue virus serotypes:

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, inactivated

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

Excipient:

Thiomersal	0.1 mg

Pinkish-white suspension for injection easily homogenised by shaking.

3. Target species

Sheep and cattle.

4. Indications for use

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. Special warnings

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 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 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 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:

No reactions other than described in the "Adverse events" section occurred following the administration of a two-fold overdose.

Special restrictions for use and special conditions for use:

Administer under veterinary control or supervision.

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 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 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
- 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 periods

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 and the vial 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 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/2/18/231/001-012

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}
{DD/MM/YYYY}
{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*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
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico de León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Tél/Tel: +32 496 585 015
E-mail: stephane.lietard@syva.es

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
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Tél/Tel: +34 987 800 800
E-mail: farmacovigilancia@syva.es

Magyarország
Local representative:
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

Contact details to report suspected adverse reactions:
Alpha-Vet Állatgyógyászati Kft
Homoksor 7., 8000 Székesfehérvár
HUNGARY
Tel: +36 30 5011484
E-mail: alpha-vet@alpha-vet.hu

Danmark
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Tlf: +34 987 800 800
E-mail: farmacovigilancia@syva.es

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:
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

Ελλάδα
Local 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

Malta
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

Nederland
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

Norge
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Tlf: +34 987 800 800
E-mail: farmacovigilancia@syva.es

Österreich
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

España
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

France
Local 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

Hrvatska
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

Ireland
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
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United Kingdom (Northern Ireland)
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