ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syvazul BTV 3 suspension for injection for sheep

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.

3.2 Indications for use for each target species

For active immunisation of sheep to reduce viraemia, mortality, 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

No information is available on the use of the vaccine in sheep 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 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.

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 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 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).

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.

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: not established.

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

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 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

LABORATORIOS SYVA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/332/001-002

8. DATE OF FIRST AUTHORISATION

20-02-2025

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

{MM/YYYY}

EXCEPTIONAL CIRCUMSTANCES:

Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.

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

SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION IN EXCEPTIONAL CIRCUMSTANCES

This being an approval in exceptional circumstances and pursuant to Article 25 of Regulation (EU) 2019/6, the MAH shall conduct, within the stated timeframe, the following measures:

Description	**Due date**
Completion of the development of the ELISA potency test for the BTV 3 antigen.	January 2026
Data from the completed stability study should be provided to confirm the proposed shelf life and the recommended storage conditions for the inactivated BTV 3 antigen and the Syvazul BTV 3 finished product.	January 2027
A study on duration of immunity in sheep should be conducted and data should be provided as soon as available.	February 2026

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 3 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

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

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

3. PACKAGE SIZE

80 ml
200 ml

4. TARGET SPECIES

Sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous 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/2/24/332/001(vial containing 80 ml)
EU/2/24/332/002 (vial containing 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 3 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

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

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

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Subcutaneous 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 3 suspension for injection for sheep

2. Composition

Each ml contains:

Active substance:

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

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

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 easily homogenised by shaking.

3. Target species

Sheep.

4. Indications for use

For active immunization 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.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

No information is available on the use of the vaccine in sheep 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.

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

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: 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 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 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*).

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:
Fendigo sa/nv
Avenue Herrmann Debrouxlaan 17
B-1160 Brüssel
Tel: + 32 2 734 48 21
E-mail: mail@fendigo.com

Contact details to report suspected adverse reactions:
Fendigo sa/nv
Tel: + 32 474 97 09 88
E-mail: PHV@fendigo.com

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:
Fendigo sa/nv
Avenue Herrmann Debrouxlaan 17
B-1160 Brüssel
Tel: + 32 2 734 48 21
E-mail: mail@fendigo.com

Contact details to report suspected adverse reactions:
Fendigo sa/nv
Tel: + 32 474 97 09 88
E-mail: PHV@fendigo.com

Magyarország
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

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:
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

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
Local representative:
Fendigo sa/nv
Avenue Herrmann Debrouxlaan 17
B-1160 Brüssel
Tel: + 32 2 734 48 21
E-mail: mail@fendigo.com

Contact details to report suspected adverse reactions:
Fendigo sa/nv
Tel: + 32 474 97 09 88
E-mail: PHV@fendigo.com

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

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

Österreich
Local 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

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

Polska
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

Portugal
Local representative:
Iapsa portuguesa pecuária, lda
Av. Do Atlântico, nª 16 – 11ª piso- Escritório 12
PT-1990-019 Lisboa

Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Tel: +351 219 747 934
E-mail: syva.portugal@syva.pt

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

România
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
Tel:+34 987 800 800
E-mail: farmacovigilancia@syva.es

Ísland
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
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Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Sími: +34 987 800 800
Netfang: farmacovigilancia@syva.es

Italia
Local representative:
Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
SPAIN
Tel:+34 987 800 800

Contact details to report suspected adverse reactions:
Virbac s.r.l.
Via Ettore Bugatti,
15 - IT-20142 Milano
Tel: +39 02 40 92 47 1

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

Slovenija
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

Slovenská 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

Suomi/Finland
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

Sverige
Local representative
Salfarm Scandinavia AB
Florettgatan 29C,
SE-254 67 Helsingborg
Tel: +46 767 834 810
scan@salfarm.com

Contact details to report suspected adverse reactions:
Salfarm Scandinavia AB
Florettgatan 29C,
SE-254 67 Helsingborg
Tel: +46 767 834 810
scan@salfarm.com

Latvija
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

United Kingdom (Northern Ireland)
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