

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC BTV Suspension for injection for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains:

Active substances:

Inactivated bluetongue virus (BTV)

One of the following inactivated bluetongue virus serotypes:

Inactivated bluetongue virus, serotype 1 (BTV-1), strain BTV-1/ALG/2006/01	$\geq 22.60 \mu\text{g/ml}$
Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004	$\geq 2.55 \mu\text{g/ml}$
Inactivated bluetongue virus, serotype 8 (BTV-8), strain BTV8/BEL/2006/01	$\geq 55.80 \mu\text{g/ml}$

Adjuvants:

Aluminium hydroxide	6 mg
Purified saponin (Quil A)	0.05 mg

Excipients:

Thiomersal	0.1 mg
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For the full list of excipients, see section 6.1.

The type of strain included in the final product will be selected based on the epidemiological situation at the time of manufacturing and will be stated on the label.

3. PHARMACEUTICAL FORM

Suspension for injection.

White or pinkish-white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle.

4.2 Indications for use, specifying the target species

Sheep

For active immunisation of sheep to prevent the viraemia* caused by bluetongue virus serotype 1 or 4 or 8) and to reduce clinical signs caused by bluetongue virus serotype 8

* Below the level of detection by the validated RT-PCR method at $1 \log_{10} \text{TCID}_{50}/\text{ml}$ for serotypes 8 and 4, and $1.3 \log_{10} \text{TCID}_{50}/\text{ml}$ for serotype 1.

Onset of immunity: 21 days after completion of the primary vaccination scheme.

Duration of immunity: 1 year after completion of the primary vaccination scheme.

Cattle

For active immunisation of cattle to prevent viraemia* caused by bluetongue virus serotype 1 or 4 or 8.

* Below the level of detection by the validated RT-PCR method at 1 log₁₀ TCID₅₀/ml for serotypes 8 and 4, and 1.3 log₁₀ TCID₅₀/ml for serotype 1.

Onset of immunity: BTV, serotype 1: 28 days after completion of the primary vaccination scheme
BTV, serotype 4: 21 days after completion of the primary vaccination scheme
BTV, serotype 8: 31 days after completion of the primary vaccination scheme

Duration of immunity: 1 year after completion of the primary vaccination scheme.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Occasionally, the presence of maternally-derived antibodies in sheep of minimum recommended age might interfere with the protection induced by the vaccine.

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

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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

Sheep:

A transient increase in rectal temperature not exceeding 1°C is common. It lasts not longer than 24 to 72 hours.

Temporary local reactions at the injection site in the format of a normally painless nodule of 0.5 to 3 cm which decreases progressively over time occur very common.

Most local reactions disappear before 14 days, although some can persist after that time.

In very rare cases, loss of appetite can occur. Hypersensitivity reactions are very rarely observed.

Cattle:

A transient increase in rectal temperature is rare.

Temporary local reactions at the injection site in the format of a normally painless nodule of 0.5 to 5 cm which decreases progressively over time occur very common.

Most local reactions disappear before 21 days, although some can persist after that time.

In very rare cases, loss of appetite can occur. Hypersensitivity reactions are very rarely observed.

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).

4.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy in ewes and cows.

Lactation:

There is no negative impact on the milk yield using the vaccine in lactating ewes and cows.

Fertility:

The safety and efficacy of the vaccines has not been established in breeding males (sheep and cattle). 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).

4.8 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.

4.9 Amounts to be administered and administration route

Subcutaneous use.

Shake well before use. Avoid multiple vial broaching. Avoid introduction of contamination.

Primary vaccination

Sheep:

Sheep from 2.5 months of age:

For monovalent vaccine containing bluetongue virus serotype 1 or serotype 4 administer one dose of 2 ml subcutaneously.

For monovalent vaccine containing bluetongue virus serotype 8 administer two doses of 2 ml subcutaneously 3 weeks apart.

Cattle:

Cattle from 2 months of age:

Administer two doses of 4 ml subcutaneously 3-4 weeks apart.

Revaccination

An annual revaccination is recommended.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

After the administration of a double dose, no adverse reactions other than those described in section 4.6 were observed.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bluetongue virus vaccines for sheep.
ATC vet code: QI04AA02.

BLUEVAC BTV stimulates active immunity of sheep and cattle against bluetongue virus serotype(s) related to those contained in the vaccine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Purified saponin (Quil A)
Thiomersal
Phosphate buffered saline (sodium chloride, disodium phosphate and potassium phosphate, water for injections)

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal products.

6.3 Shelf life

Shelf life formulation with Bluetongue virus serotype 1: 18 months
Shelf life formulation with Bluetongue virus serotype 4 or 8: 2 years

Shelf life after first opening the immediate packaging: 10 hours

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles of 52 ml, 100 ml or 252 ml with bromobutyl stoppers and aluminium seals.

Package sizes:
Cardboard box with 1 bottle containing 52 ml.
Cardboard box with 1 bottle containing 100 ml
Cardboard box with 1 bottle containing 252 ml

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/122/001
EU/2/11/122/002
EU/2/11/122/003
EU/2/11/122/004
EU/2/11/122/005
EU/2/11/122/006
EU/2/11/122/007
EU/2/11/122/008
EU/2/11/122/009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14/04/2011
Date of last renewal: 15/03/2016

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use of BLUEVAC BTV 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.

ANNEX II

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**
- D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substance

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

Name and address of the manufacturer responsible for batch release

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

- a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.
- b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

**D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING
AUTHORISATION**

The current annual reporting cycle for periodic safety update reports (PSURs) should be maintained.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (52 ml, 100 ml and 252 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC BTV Suspension for injection for cattle and sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of vaccine contains:

BTV1 antigen $\geq 22.60 \mu\text{g}$

BTV4 antigen $\geq 2.55 \mu\text{g}$

BTV8 antigen $\geq 55.80 \mu\text{g}$

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

52ml

100 ml

252 ml

5. TARGET SPECIES

Sheep and cattle.

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Subcutaneous use.

Shake well before use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

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

CZ Vaccines S.A.U.

36410 O Porriño – Spain

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/122/001 bottle of 52 ml
EU/2/11/122/002 bottle of 100 ml
EU/2/11/122/003 bottle of 252 ml
EU/2/11/122/004 bottle of 52 ml
EU/2/11/122/005 bottle of 100 ml
EU/2/11/122/006 bottle of 252 ml
EU/2/11/122/007 bottle of 52 ml
EU/2/11/122/008 bottle of 100 ml
EU/2/11/122/009 bottle of 252 ml

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml and 252 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC BTV Suspension for injection for cattle and sheep

2. STATEMENT OF ACTIVE SUBSTANCES

BTV1 antigen $\geq 22.60 \mu\text{g/ml}$

BTV4 antigen $\geq 2.55 \mu\text{g /ml}$

BTV8 antigen $\geq 55.80 \mu\text{g/ml}$

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

252 ml

5. TARGET SPECIES

Sheep and cattle.

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

SC

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

CZ Vaccines S.A.U.
36410 O Porriño – Spain

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/122/002 bottle of 100 ml
EU/2/11/122/003 bottle of 252 ml
EU/2/11/122/005 bottle of 100 ml
EU/2/11/122/006 bottle of 252 ml
EU/2/11/122/008 bottle of 100 ml
EU/2/11/122/009 bottle of 252 ml

17. MANUFACTURER’S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 52 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC BTV Suspension for injection for cattle and sheep

2. QUANTITY OF THE ACTIVE SUBSTANCE

BTV1 antigen $\geq 22.60 \mu\text{g/ml}$

BTV4 antigen $\geq 2.55 \mu\text{g /ml}$

BTV8 antigen $\geq 55.80 \mu\text{g/ml}$

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

52 ml

4. ROUTE OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP {month/year}

Once opened, use within 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
BLUEVAC BTV Suspension for injection for cattle and sheep

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

Marketing authorisation holder and manufacturer responsible for batch release:

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC BTV Suspension for injection for cattle and sheep

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

Each ml of vaccine contains:

Active substances:

Inactivated bluetongue virus (BTV)

One of the following inactivated bluetongue virus serotypes:

Inactivated bluetongue virus, serotype 1 (BTV-1), strain BTV-1/ALG/2006/01	≥ 22.60 µg/ml
Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004	≥ 2.55 µg/ml
Inactivated bluetongue virus, serotype 8 (BTV-8), strain BTV8/BEL/2006/01	≥ 55.80 µg/ml

Adjuvants:

Aluminium hydroxide	6 mg
Purified saponin (Quil A)	0.05 mg

Excipient:

Thiomersal	0.1 mg
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The type of strain included in the final product will be selected based on the epidemiological situation at the time of manufacturing and will be stated on the label.

White or pinkish-white suspension.

4. INDICATION(S)

Sheep

For active immunisation of sheep to prevent the viraemia* caused by bluetongue virus serotype 1 or 4 or 8) and to reduce clinical signs caused by bluetongue virus serotype 8.

* Below the level of detection by the validated RT-PCR method at 1 log₁₀ TCID₅₀/ml for serotypes 8 and 4, and 1.3 log₁₀ TCID₅₀/ml for serotype 1

Onset of immunity: 21 days after completion of the primary vaccination scheme.

Duration of immunity: 1 year after completion of the primary vaccination scheme.

Cattle

For active immunisation of cattle to prevent viraemia* caused by bluetongue virus serotype 1 or 4 or 8

* Below the level of detection by the validated RT-PCR method at 1 log₁₀ TCID₅₀/ml for serotypes 8 and 4, and 1.3 log₁₀ TCID₅₀/ml for serotype 1.

Onset of immunity: BTV, serotype 1: 28 days after completion of the primary vaccination scheme
BTV, serotype 4: 21 days after completion of the primary vaccination scheme
BTV, serotype 8: 31 days after completion of the primary vaccination scheme

Duration of immunity: 1 year after completion of the primary vaccination scheme.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Sheep:

A transient increase in rectal temperature not exceeding 1°C is common. It lasts not longer than 24 to 72 hours.

Temporary local reactions at the injection site in the format of a normally painless nodule of 0.5 to 3 cm which decreases progressively over time occur very common.

Most local reactions disappear before 14 days, although some can persist after that time.

In very rare cases, loss of appetite can occur. Hypersensitivity reactions are very rarely observed.

Cattle:

A transient increase in rectal temperature is rare.

Temporary local reactions at the injection site in the format of a normally painless nodule of 0.5 to 5 cm which decreases progressively over time occur very common.

Most local reactions disappear before 21 days, although some can persist after that time.

In very rare cases, loss of appetite can occur. Hypersensitivity reactions are very rarely observed.

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

Subcutaneous use.

Primary vaccination

Sheep:

Sheep from 2.5 months of age:

For monovalent vaccine containing bluetongue virus serotype 1 or serotype 4 administer one dose of 2 ml subcutaneously.

For monovalent vaccine containing bluetongue virus serotype 8 administer two doses of 2 ml subcutaneously 3 weeks apart.

Cattle:

Cattle from 2 months of age:

Administer two doses of 4 ml subcutaneously with a 3 - 4 weeks apart.

Revaccination

An annual revaccination is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use. Avoid multiple vial broaching. Avoid introduction of contamination.

10. WITHDRAWAL PERIOD(S)

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton.

Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species

Vaccinate healthy animals only.

Occasionally, the presence of maternally-derived antibodies in sheep of minimum recommended age might interfere with the protection induced by the vaccine.

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

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.

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.

Pregnancy:

Can be used during pregnancy in ewes and cows.

Lactation:

There is no negative impact on the milk yield using the vaccine in lactating ewes and cows.

Fertility:

The safety and efficacy of the vaccine has not been established in breeding males (sheep and cattle). 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 the administration of a double dose, no adverse reactions other than those described in section 6 were observed.

Incompatibilities:

Do not mix with any other veterinary medicinal products.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

15. OTHER INFORMATION

Pharmacotherapeutic group: Bluetongue virus vaccines, inactivated.
ATC vet code: QI04AA02

BLUEVAC BTV stimulates active immunity of sheep and cattle against bluetongue virus, serotype (s) related to those contained in the vaccine.

Pack sizes:

Cardboard box of 1 bottle containing 52 ml

Cardboard box of 1 bottle containing 100 ml

Cardboard box of 1 bottle containing 252ml

Not all pack sizes may be marketed.

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

Nederland

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A Relva s/n – Torneiros
36410 O Porriño
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Tel: +34 986330400

België/Belgique/Belgien

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3621 ZB Breukelen
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A Relva s/n – Torneiros
36410 O Porriño
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Ελλάδα

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Deutschland, Ireland, United Kingdom (Northern Ireland), Luxembourg/Luxemburg, Република България, Magyarország, Česká republika, Malta, Danmark, Norge, Eesti, Österreich, Polska, Portugal, România, Slovenija, Ísland, Slovenská republika, Suomi/Finland, Κύπρος, Sverige, Latvija, Lietuva, Hrvatska

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