ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	Each dose of 2 ml contains (BTV-1, BTV-4, BTV-8 in sheep; BTV-1, BTV-8 in cattle):	**Each dose of 4 ml contains** (BTV-4 in cattle):
Active substances:		
One of the following inactivated bluetongue virus strains.		
Inactivated bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1	RP* ≥ 1	n.a.
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02	RP* ≥ 1	n.a.
Inactivated bluetongue virus, serotype 4, strain SPA-1/2004	RP* ≥ 0.8	RP* ≥ 0.8

n.a.: not applicable

*Relative potency by a mice potency test compared to a reference vaccine efficacious in sheep and/or cattle.

The type of strain 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. The target species will also be shown on the label.

Adjuvants:

Al^{3+} (as hydroxide)	4 mg	8 mg
Quil-A (*Quillaja saponaria* saponin extract)	0.4 mg	0.8 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**	
	Each dose of 2 ml contains (BTV-1, BTV-4, BTV-8 in sheep; BTV-1, BTV-8 in cattle):	**Each dose of 4 ml contains** (BTV-4 in cattle):
Thiomersal	0.2 mg	0.4 mg
Potassium chloride		
Potassium dihydrogen phosphate		
Disodium phosphate dihydrate		
Sodium chloride		
Water for injections		

Off-white or pink liquid.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and cattle.

3.2 Indications for use for each target species

Sheep:
Active immunisation of sheep from 6 weeks of age for the prevention* of viraemia caused by bluetongue virus, serotype 1 or serotype 8.

Active immunisation of sheep from 6 weeks of age for the reduction* of viraemia caused by bluetongue virus, serotype 4.

*Below the level of detection of < 3.9 $\log_{10}$ genome copies/ml by the validated RT-qPCR method, indicating no presence of viral genome.

Onset of immunity: 3 weeks after completion of the primary vaccination scheme.
Duration of immunity: 1 year after completion of the primary vaccination scheme.

Cattle:
Active immunisation of cattle from 12 weeks of age for the prevention** of viraemia caused by bluetongue virus, serotype 1, serotype 4 or serotype 8.

**Below the level of detection of < 3.4 $\log_{10}$ genome copies/ml by a validated RT-qPCR method, indicating no presence of viral genome.

Onset of immunity:	Bluetongue virus, serotype 1: 15 days after completion of the primary vaccination scheme. Bluetongue virus, serotype 8: 25 days after completion of the primary vaccination scheme. Bluetongue virus, serotype 4: 14 days after completion of the primary vaccination scheme.
Duration of immunity:	Bluetongue virus, serotype 1: 1 year after completion of the primary vaccination scheme. Bluetongue virus, serotype 8: 1 year after completion of the primary vaccination scheme. Bluetongue virus, serotype 4: 6 months after completion of the primary vaccination scheme.

There is evidence of BTV-1 seroneutralising antibodies indicative of protection for up to 21 months after primary vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

No information is available on the use of the vaccine in seropositive animals including those 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.

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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2] Injection site nodule[3]

[1]Transient, not exceeding 1.6 °C, observed during the 48 hours following vaccination.
[2]Diffuse swelling, persisting for not more than 7 days.
[3]Palpable granuloma, up to a size of 60 cm^2, decreasing in size over time but possibly persisting for more than 50 days.

Cattle administered a 2 ml dose:

Very common (>1 animal / 10 animals treated):	Injection site reaction[1]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature[2]

[1]Local reactions of up to 5 cm diameter were very commonly observed and reactions > 5 cm diameter were commonly observed. These resolved within a maximum of 25 days. Local reactions may increase slightly following the second dose, in this case lasting up to 15 days.
[2]Transient, not exceeding 2.7 °C, observed during the 48 hours following vaccination.

Cattle administered a 4 ml dose:

Very common (>1 animal / 10 animals treated):	Injection site reaction[1] Elevated temperature[2]

[1]Up to 6 cm in diameter, resolved in a maximum of 8 days.
[2]Transient, not exceeding 2.7 °C, observed within the 48 hours following vaccination with a maximum duration of 2 days.

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:
Can be used during pregnancy.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation in sheep. Can be used during lactation in cattle.

Fertility:
The safety and the efficacy of the veterinary medicinal product 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

Sheep:

Subcutaneous use.

Primary vaccination:
Administer two doses of 2 ml according to the following vaccination scheme:
- 1st dose: from 6 weeks of age.
- 2nd dose: after 3 weeks.

Re-vaccination scheme:
For protection against serotype 1 or serotype 8, administer one dose of 2 ml, every year.
For protection against serotype 4, administer two doses of 2 ml three weeks apart, every year.

Cattle:

Intramuscular use.

For protection against serotype 1 and serotype 8:

Primary vaccination:
Administer two doses of 2 ml according to the following vaccination scheme:
- 1st dose: from 12 weeks of age.
- 2nd dose: after 3 weeks.

Re-vaccination scheme:
For protection against serotype 1, administer one dose of 2 ml, every year.
For protection against serotype 8, administer two doses of 2 ml three weeks apart, every year.

For protection against serotype 4:

Primary vaccination:
Administer two doses of 4 ml according to the following vaccination scheme:
- 1st dose: from 12 weeks of age.
- 2nd dose: after 3 weeks.

Re-vaccination scheme:
Administer two doses of 4 ml three weeks apart, every 6 months.

Method of administration (sheep and cattle):
Apply usual aseptic procedures.
Shake gently immediately before use.
Avoid bubble formation, as this can be irritating at the site of injection.
The entire content of the bottle should be used immediately after broaching and during the same procedure.
In order to avoid accidental contamination of the vaccine during use, it is recommended to use a multi-injection type vaccination system when larger dose presentations are used.

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

Sheep:

After administration with a 2-fold overdose (4 ml), reactions in sheep are similar to those seen after administration of a single dose, but injection site reactions may persist for a longer time (general swelling at the injection site persisting for not more than 9 days or subcutaneous granuloma possibly persisting for more than 63 days).

Cattle:

A transient increase in rectal temperature, not exceeding 2 °C, may occur in 10% of the animals during the 24 hours following administration of a 2-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

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: QI02AA08

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

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: 1 year (Bluetongue virus, serotype 1 and serotype 8) or 18 months (Bluetongue virus, serotype 4).

Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles of 20, 100 or 240 ml with chlorobutyl elastomer stopper and aluminium seal.

Pack sizes:
Cardboard box with 1 bottle of 10 doses of 2 ml or 5 doses of 4 ml (20 ml).
Cardboard box with 1 bottle of 50 doses of 2 ml or 25 doses of 4 ml (100 ml).
Cardboard box with 1 bottle of 120 doses of 2 ml or 60 doses of 4 ml (240 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

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/207/001–009

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 25/04/2017.

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

{DD/MM/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 BTV-1 for sheep and cattle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV Suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Inactivated BTV, serotype 1.

3. PACKAGE SIZE

20 ml (10 doses)
100 ml (50 doses)
240 ml (120 doses)

4. TARGET SPECIES

Sheep and cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use (sheep) or intramuscular use (cattle).

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the 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

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/207/001 (20 ml) BTV 1
EU/2/17/207/002 (100 ml) BTV 1
EU/2/17/207/003 (240 ml) BTV 1

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX BTV-4 for sheep and cattle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV Suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml (sheep) or 4 ml (cattle) contains:
Inactivated BTV, serotype 4.

3. PACKAGE SIZE

20 ml (10 doses for sheep, 5 doses for cattle)
100 ml (50 doses for sheep, 25 doses for cattle)
240 ml (120 doses for sheep, 60 doses for cattle)

4. TARGET SPECIES

Sheep and cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use (sheep) or intramuscular use (cattle).

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

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

Read the 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

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/207/004 (20 ml) BTV 4
EU/2/17/207/005 (100 ml) BTV 4
EU/2/17/207/006 (240 ml) BTV 4

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX BTV-8 for sheep and cattle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV Suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Inactivated BTV, serotype 8.

3. PACKAGE SIZE

20 ml (10 doses)
100 ml (50 doses)
240 ml (120 doses)

4. TARGET SPECIES

Sheep and cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use (sheep) or intramuscular use (cattle).

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the 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

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/207/007 (20 ml) BTV 8
EU/2/17/207/008 (100 ml) BTV 8
EU/2/17/207/009 (240 ml) BTV 8

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml and 240 ml (BTV-1 for sheep and cattle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV Suspension for injection.

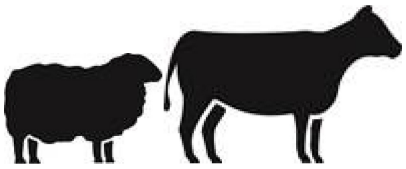
2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Inactivated BTV, serotype 1.

100 ml (50 doses)
240 ml (120 doses)

3. TARGET SPECIES

Sheep and cattle.



4. ROUTES OF ADMINISTRATION

Subcutaneous use (sheep) or intramuscular use (cattle).
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml and 240 ml (BTV-4 for sheep and cattle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV Suspension for injection.

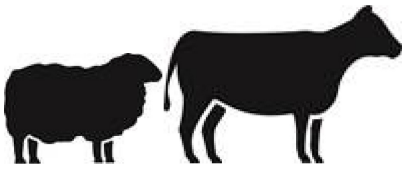
2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml (sheep) or 4 ml (cattle) contains:
Inactivated BTV, serotype 4.

100 ml (50 doses for sheep, 25 doses for cattle)
240 ml (120 doses for sheep, 60 doses for cattle)

3. TARGET SPECIES

Sheep and cattle.



4. ROUTES OF ADMINISTRATION

Subcutaneous use (sheep) or intramuscular use (cattle).
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml and 240 ml (BTV-8 for sheep and cattle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV Suspension for injection.

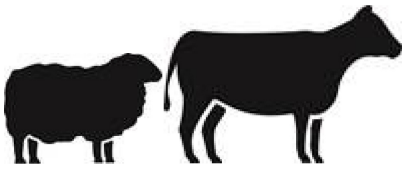
2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Inactivated BTV, serotype 8.

100 ml (50 doses)
240 ml (120 doses)

3. TARGET SPECIES

Sheep and cattle.



4. ROUTES OF ADMINISTRATION

Subcutaneous use (sheep) or intramuscular use (cattle).
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

9. BATCH NUMBER

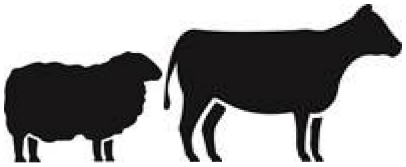
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 20 ml (BTV-1 for sheep and cattle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated BTV, serotype 1.

20 ml (10 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

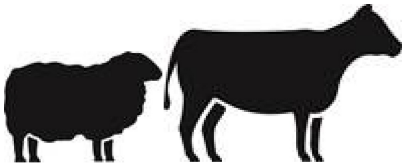
Exp. {mm/yyyy}
Once broached use immediately.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 20 ml (BTV-4 for sheep and cattle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated BTV, serotype 4.

20 ml (10 doses for sheep, 5 doses for cattle)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

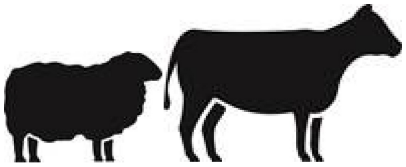
Exp. {mm/yyyy}
Once broached use immediately.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 20 ml (BTV-8 for sheep and cattle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated BTV, serotype 8.

20 ml (10 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zulvac BTV suspension for injection for sheep and cattle

2. Composition

	Each dose of 2 ml contains (BTV-1, BTV-4, BTV-8 in sheep; BTV-1, BTV-8 in cattle):	**Each dose of 4 ml contains** (BTV-4 in cattle):
Active substances:		
One of the following inactivated bluetongue virus strains.		
Inactivated bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1	RP* ≥ 1	n.a.
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02	RP* ≥ 1	n.a.
Inactivated bluetongue virus, serotype 4, strain SPA-1/2004	RP* ≥ 0.8	RP* ≥ 0.8

n.a.: not applicable

*Relative potency by a mice potency test compared to a reference vaccine efficacious in sheep and/or cattle.

The type of strain 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. The target species will also be shown on the label.

Adjuvants:		
Al^{3+} (as hydroxide)	4 mg	8 mg
Quil-A (*Quillaja saponaria* saponin extract)	0.4 mg	0.8 mg
Excipients:		
Thiomersal	0.2 mg	0.4 mg

Off-white or pink liquid.

3. Target species

Sheep and cattle.

4. Indications for use

Sheep:
Active immunisation of sheep from 6 weeks of age for the prevention* of viraemia caused by bluetongue virus, serotype 1 or serotype 8.

Active immunisation of sheep from 6 weeks of age for the reduction* of viraemia caused by bluetongue virus, serotype 4.

*Below the level of detection of < 3.9 $\log_{10}$ genome copies/ml by the validated RT-qPCR method, indicating no presence of viral genome.

Onset of immunity: 3 weeks after completion of the primary vaccination scheme.
Duration of immunity: 1 year after completion of the primary vaccination scheme.

Cattle:
Active immunisation of cattle from 12 weeks of age for the prevention** of viraemia caused by bluetongue virus, serotype 1, serotype 4 or serotype 8.

**Below the level of detection of < 3.4 $\log_{10}$ genome copies/ml by a validated RT-qPCR method, indicating no presence of viral genome.

Onset of immunity: Bluetongue virus, serotype 1: 15 days after completion of the primary vaccination scheme.
Bluetongue virus, serotype 8: 25 days after completion of the primary vaccination scheme.
Bluetongue virus, serotype 4: 14 days after completion of the primary vaccination scheme.

Duration of immunity: Bluetongue virus, serotype 1: 1 year after completion of the primary vaccination scheme.
Bluetongue virus, serotype 8: 1 year after completion of the primary vaccination scheme.
Bluetongue virus, serotype 4: 6 months after completion of the primary vaccination scheme.

There is evidence of BTV-1 seroneutralising antibodies indicative of protection for up to 21 months after primary vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
No information is available on the use of the vaccine in seropositive animals including those 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.

Pregnancy:
Can be used during pregnancy.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation in sheep. Can be used during lactation in cattle.

Fertility:
The safety and the efficacy of the veterinary medicinal product 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:
Sheep:
After administration with a 2-fold overdose (4 ml), reactions in sheep are similar to those seen after administration of a single dose, but injection site reactions may persist for a longer time (general swelling at the injection site persisting for not more than 9 days or subcutaneous granuloma possibly persisting for more than 63 days).

Cattle:
A transient increase in rectal temperature, not exceeding 2 °C, may occur in 10% of the animals during the 24 hours following administration of a 2-fold overdose.

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):
Elevated temperature[1] Injection site swelling[2] Injection site nodule[3]

[1]Transient, not exceeding 1.6 °C, observed during the 48 hours following vaccination.
[2]Diffuse swelling, persisting for not more than 7 days.
[3]Palpable granuloma, up to a size of 60 cm^2, decreasing in size over time but possibly persisting for more than 50 days.

Cattle administered a 2 ml dose:

Very common (>1 animal / 10 animals treated):
Injection site reaction[1]
Common (1 to 10 animals / 100 animals treated):
Elevated temperature[2]

[1]Local reactions of up to 5 cm diameter were very commonly observed and reactions > 5 cm diameter were commonly observed. These resolved within a maximum of 25 days. Local reactions may increase slightly following the second dose, in this case lasting up to 15 days.
[2]Transient, not exceeding 2.7 °C, observed during the 48 hours following vaccination.

Cattle administered a 4 ml dose:

Very common (>1 animal / 10 animals treated):
Injection site reaction[1] Elevated temperature[2]

[1]Up to 6 cm in diameter, resolved in a maximum of 8 days.
[2]Transient, not exceeding 2.7 °C, observed within the 48 hours following vaccination with a maximum duration of 2 days.

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.

Primary vaccination:
Administer two doses of 2 ml according to the following vaccination scheme:
- 1st dose: from 6 weeks of age.
- 2nd dose: after 3 weeks.

Re-vaccination scheme:
For protection against serotype 1 or serotype 8, administer one dose of 2 ml, every year.
For protection against serotype 4, administer two doses of 2 ml three weeks apart, every year.

Cattle:

Intramuscular use.

For protection against serotype 1 and serotype 8:

Primary vaccination:
Administer two doses of 2 ml according to the following vaccination scheme:
- 1st dose: from 12 weeks of age.
- 2nd dose: after 3 weeks.

Re-vaccination scheme:
For protection against serotype 1, administer one dose of 2 ml, every year.
For protection against serotype 8, administer two doses of 2 ml three weeks apart, every year.

For protection against serotype 4:

Primary vaccination:
Administer two doses of 4 ml according to the following vaccination scheme:
- 1st dose: from 12 weeks of age.
- 2nd dose: after 3 weeks.

Re-vaccination scheme:
Administer two doses of 4 ml three weeks apart, every 6 months.

9. Advice on correct administration

Apply usual aseptic procedures. Shake gently immediately before use.
Avoid bubble formation, as this can be irritating at the site of injection.
The entire content of the bottle should be used immediately after broaching and during the same procedure.
In order to avoid accidental contamination of the vaccine during use, it is recommended to use a multi-injection type vaccination system when larger dose presentations are used.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: use immediately.

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/2/17/207/001–009

Cardboard box with 1 bottle of 10 doses of 2 ml or 5 doses of 4 ml (20 ml).
Cardboard box with 1 bottle of 50 doses of 2 ml or 25 doses of 4 ml (100 ml).
Cardboard box with 1 bottle of 120 doses of 2 ml or 60 doses of 4 ml (240 ml).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/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:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Tél/Tel: +32 (0) 800 99 189
pharmvig-belux@zoetis.com

Република България
Тел: +359 888 51 30 30
zoetisromania@zoetis.com

Česká republika
Tel: +420 257 101 111
infovet.cz@zoetis.com

Danmark
Tlf: +45 70 20 73 05
adr.scandinavia@zoetis.com

Deutschland
Tel: +49 30 2020 0049
tierarzneimittelsicherheit@zoetis.com

Eesti
Tel: +370 610 05088
zoetis.estonia@zoetis.com

Ελλάδα
Τηλ: +30 210 6791900
infogr@zoetis.com

Lietuva
Tel: +370 610 05088
zoetis.lithuania@zoetis.com

Luxembourg/Luxemburg
Tél/Tel: +32 (2) 746 80 11
pharmvig-belux@zoetis.com

Magyarország
Tel.: +36 1 224 5200
hungary.info@zoetis.com

Malta
Tel: +356 21 465 797
info@agrimedltd.com

Nederland
Tel: +31 (0)10 714 0900
pharmvig-nl@zoetis.com

Norge
Tlf: +47 23 29 86 80
adr.scandinavia@zoetis.com

Österreich
Tel: +43 (0)1 2701100 100
tierarzneimittelsicherheit@zoetis.com

España
Tel: +34 91 4191900
regulatory.spain@zoetis.com

France
Tél: +33 (0)800 73 00 65
contacteznous@zoetis.com

Hrvatska
Tel: +385 1 6441 462
pv.westernbalkans@zoetis.com

Ireland
Tel: +353 (0) 1 256 9800
PVSupportIreland@zoetis.com

Ísland
Sími: +45 70 20 73 05
adr.scandinavia@zoetis.com

Italia
Tel: +39 06 3366 8111
farmacovigilanza.italia@zoetis.com

Κύπρος
Τηλ: +30 210 6791900
infogr@zoetis.com

Latvija
Tel: +370 610 05088
zoetis.latvia@zoetis.com

Polska
Tel.: +48 22 2234800
pv.poland@zoetis.com

Portugal
Tel: +351 21 042 72 00
zoetis.portugal@zoetis.com

România
Tel: +40785019479
zoetisromania@zoetis.com

Slovenija
Tel: +385 1 6441 462
pv.westernbalkans@zoetis.com

Slovenská republika
Tel: +420 257 101 111
infovet.cz@zoetis.com

Suomi/Finland
Puh/Tel: +358 10 336 7000
laaketurva@zoetis.com

Sverige
Tel: +46 (0) 76 760 0677
adr.scandinavia@zoetis.com

United Kingdom (Northern Ireland)
Tel: +353 (0) 1 256 9800
pvsupportireland@zoetis.com

17. Other information

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