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 of vaccine contains:

Active substances:

One of the following inactivated bluetongue virus strains:	
Inactivated bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1	RP* ≥ 1
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02	RP* ≥ 1
Inactivated bluetongue virus, serotype 4, strain SPA-1/2004	RP** ≥ 0.8

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

**Relative potency by a mice potency test compared to a reference vaccine efficacious in sheep.

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
Quil-A (*Quillaja saponaria* saponin extract)	0.4 mg

Excipients:

Thiomersal	0.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Off-white or pink liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle

4.2 Indications for use, specifying the 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: 21 days after completion of the primary vaccination scheme.
Duration of immunity: 12 months 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 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.
Duration of immunity:	Bluetongue virus, serotype 1: 12 months after completion of the primary vaccination scheme. Bluetongue virus, serotype 8: 12 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Sheep:
A transient increase in rectal temperature, not exceeding 1.6 °C, may very commonly occur during the 48 hours following vaccination.
A local reaction at the injection site may occur very commonly after vaccination. These reactions take the form in most cases of a diffuse swelling of the injection site (persisting for not more than 7 days)

or of palpable nodules up to a size of 60 cm^2 (subcutaneous granuloma, decreasing in size over time but possibly persisting for more than 50 days).

Cattle:
A transient increase in rectal temperature, not exceeding 2.7 °C, was commonly observed during the 48 hours following vaccination in field safety studies.
Local reactions of < 2 cm diameter were very commonly observed while reactions of up to 5 cm diameter were commonly observed after administration of a single dose in field safety studies. 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. Local reactions of up to 5 cm diameter were very commonly observed and reactions > 5 cm diameter were commonly observed after repeated administration of a single dose in field safety studies.

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 sheep and cattle.

Lactation:
The safety of the vaccine has not been established during lactation in sheep. It can be used during lactation in cattle.

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).

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

Sheep:
Subcutaneous use.

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

Revaccination
For protection against serotype 1 or serotype 8, administer one dose of 2 ml, every 12 months.
For protection against serotype 4, administer two doses of 2 ml three weeks apart, every 12 months.

Cattle:
Intramuscular use.

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

Revaccination
For protection against serotype 1, administer one dose of 2 ml, every 12 months.
For protection against serotype 8, administer two doses of 2 ml three weeks apart, every 12 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.
Avoid multiple broaching.

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.

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

Sheep:
After administration with a double dose (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 two-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Bovidae, inactivated viral vaccines for cattle.
ATCvet code: QI02AA.
To stimulate 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
Quil-A (*Quillaja saponaria* saponin extract)
Thiomersal
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Sodium chloride

Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.
Shelf life after first opening the immediate packaging: use immediately.

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 20, 100 or 240 ml with chlorobutyl elastomer stopper and aluminium seal.

Pack sizes:
Cardboard box with 1 bottle of 10 doses (20 ml).
Cardboard box with 1 bottle of 50 doses (100 ml).
Cardboard box with 1 bottle of 120 doses (240 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

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/207/001–009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25/04/2017.

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 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.

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
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodon s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

Name and address of the manufacturer responsible for batch release
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodon s/n "la Riba"
17813 Vall de Bianya
Girona
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.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of bluetongue.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

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

Full stability data for three batches of monovalent BTV-4 vaccine within 39 months of the granting of the Marketing Authorisation shall be provided.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 1 x 20 ml, 1 x 100 ml and 1 x 240 ml
(BTV-1 for sheep and cattle; BTV-8 for sheep and cattle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
Inactivated BTV, serotype 1
Inactivated BTV, serotype 8
Al^{3+} (as hydroxide), Quil-A (*Quillaja saponaria* saponin extract), thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Sheep and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

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
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

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 1 x 20 ml, 1 x 100 ml and 1 x 240 ml (BTV-4 for sheep)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV suspension for injection for sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
Inactivated BTV, serotype 4
Al^{3+} (as hydroxide), Quil-A (*Quillaja saponaria* saponin extract), thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml and 240 ml (BTV-1 for sheep and cattle; BTV-8 for sheep and cattle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
Inactivated BTV, serotype 1
Inactivated BTV, serotype 8
Al^{3+} (as hydroxide), Quil-A (*Quillaja saponaria* saponin extract), thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Sheep and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/207/002 (100 ml) BTV 1
EU/2/17/207/003 (240 ml) BTV 1
EU/2/17/207/008 (100 ml) BTV 8
EU/2/17/207/009 (240 ml) BTV 8

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV suspension for injection for sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:
Inactivated BTV, serotype 4
Al^{3+} (as hydroxide), Quil-A (*Quillaja saponaria* saponin extract), thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 20 ml (BTV-1 for sheep and cattle; BTV-8 for sheep and cattle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV suspension for injection for sheep and cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose of 2 ml:
Inactivated BTV, serotype 1
Inactivated BTV, serotype 8

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

20 ml (10 doses)

4. ROUTE(S) OF ADMINISTRATION

SC (sheep) / IM (cattle)

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 20 ml (BTV-4 for sheep)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV suspension for injection for sheep

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose of 2 ml:
Inactivated BTV, serotype 4

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

20 ml (10 doses)

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Once broached, use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Zulvac BTV suspension for injection for sheep and cattle

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

Marketing authorisation holder:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodon s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV suspension for injection for sheep and cattle

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

Each dose of 2 ml of vaccine contains:

Active substances:
One of the following inactivated bluetongue virus strains:

Inactivated bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1	RP* ≥ 1
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02	RP* ≥ 1
Inactivated bluetongue virus, serotype 4, strain SPA-1/2004	RP** ≥ 0.8

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

**Relative potency by a mice potency test compared to a reference vaccine efficacious in sheep.

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
Quil-A (*Quillaja saponaria* saponin extract)	0.4 mg

Excipient:

Thiomersal	0.2 mg

Off-white or pink liquid.

4. INDICATION(S)

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: 21 days after completion of the primary vaccination scheme.
Duration of immunity: 12 months 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 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.
Duration of immunity:	Bluetongue virus, serotype 1: 12 months after completion of the primary vaccination scheme. Bluetongue virus, serotype 8: 12 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. ADVERSE REACTIONS

Sheep:
A transient increase in rectal temperature, not exceeding 1.6 °C, may very commonly occur during the 48 hours following vaccination.
A local reaction at the injection site may occur very commonly after vaccination. These reactions take the form in most cases of a diffuse swelling of the injection site (persisting for not more than 7 days) or of palpable nodules up to a size of 60 cm^2 (subcutaneous granuloma, decreasing in size over time but possibly persisting for more than 50 days).

Cattle:
A transient increase in rectal temperature, not exceeding 2.7 °C, was commonly observed during the 48 hours following vaccination in field safety studies.
Local reactions of < 2 cm diameter were very commonly observed while reactions of up to 5 cm diameter were commonly observed after administration of a single dose in field safety studies. These resolved within a maximum of 25 days. Local reactions may increase slightly following the second

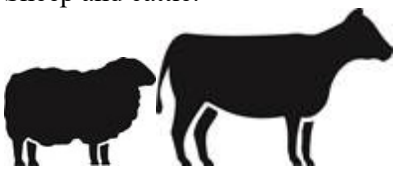
dose, in this case lasting up to 15 days. Local reactions of up to 5 cm diameter were very commonly observed and reactions > 5 cm diameter were commonly observed after repeated administration of a single dose in field safety studies.

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

Sheep:
Subcutaneous use.

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

Revaccination:
For protection against serotype 1 or serotype 8, administer one dose of 2 ml, every 12 months.
For protection against serotype 4, administer two doses of 2 ml three weeks apart, every 12 months.

Cattle:
Intramuscular use.

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

Revaccination:
For protection against serotype 1, administer one dose of 2 ml, every 12 months.
For protection against serotype 8, administer two doses of 2 ml three weeks apart, every 12 months.

9. ADVICE ON CORRECT ADMINISTRATION

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.

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.
Avoid multiple broaching.

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 after EXP.

Shelf life after first opening the container: use immediately.

12. SPECIAL WARNINGS

Special warnings for each target species:
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 seropositive animals including those with maternally derived antibodies.

Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Pregnancy:
Can be used during pregnancy in sheep and cattle.

Lactation:
The safety of the vaccine has not been established during lactation in sheep. It can be used during lactation in cattle.

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 (symptoms, emergency procedures, antidotes):
Sheep:
After administration with a double dose (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 two-fold overdose.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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 product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Pack sizes:
Cardboard box with 1 bottle of 10 doses (20 ml).
Cardboard box with 1 bottle of 50 doses (100 ml).
Cardboard box with 1 bottle of 120 doses (240 ml).

Not all pack sizes may be marketed.

Any person intending to manufacture, import, possess, 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.