ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR suspension for injection for sheep and cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances *:
Inactivated bluetongue virus ≥ strain specific pass level (log10 pixels) **
(*) maximum of two different inactivated bluetongue virus serotypes

(**)Strain-specific pass levels	(**) Antigen content (VP2 protein) by immuno-assay
BTV1	1.9 log10 pixels/mL
BTV2	1.82 log10 pixels/mL
BTV4	1.86 log10 pixels/mL
BTV8	2.12 log10 pixels/mL

A confirmatory final potency test by seroneutralisation in rats is conducted when a batch is released.

Adjuvants:
Aluminium hydroxide (Al^{3+}) 2.7 mg
Saponin 30 HU**
(**) Haemolytic units

Excipients:

Qualitative composition of excipients and other constituents
Silicon antifoam
Phosphate buffer
Glycine buffer

The type of strain(s) (two strains at most) 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.

Appearance: homogeneous milky white.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and cattle

3.2 Indications for use for each target species

Active immunisation of sheep to prevent viraemia* and to reduce clinical signs caused by bluetongue virus serotypes 1, 2, 4 and/or 8 (combination of maximum 2 serotypes).
Active immunisation of cattle to prevent viraemia* caused by bluetongue virus serotypes 1, 2, 4 and/or 8, and to reduce clinical signs caused by bluetongue virus serotypes 1, 4 and/or 8 (combination of maximum 2 serotypes).
*below the level of detection by the validated RT-PCR method at 3.68 $\log_{10}$ RNA copies/ml, indicating no infectious virus transmission.

Onset of immunity: 3 weeks (or 5 weeks in sheep for BTV2) after the primary vaccination course for BTV-1, BTV-2 (cattle), BTV-4 and BTV-8 serotypes.
Duration of immunity: 1 year after primary vaccination course.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

If used in other domestic and wild ruminant species that are considered at risk of infection, its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of animals prior to mass vaccination. The level of efficacy for other species may differ from that observed in sheep and cattle.

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 and cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions; Injection site swelling[1]; Elevated temperature[2].

[1]at most 32 cm² in cattle and 24 cm^2 in sheep, which becomes residual 35 days later (≤ 1 cm^2)
[2]not exceeding 1.7°C (with an average of 1.1 ºC), may occur within 24 hours after vaccination

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 section “Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Fertility:
The safety and the efficacy of the vaccine have not been established in breeding males. In this category of animals the vaccine should be used only according to the benefit/risk assessment by the responsible veterinarian and/ or national Competent Authorities on the current vaccination policies against Bluetongue Virus (BTV).

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

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 vial broaching.

Administer one dose of 1 ml subcutaneously according to the following vaccination scheme:

- **Primary vaccination**

In sheep:
- First injection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune sheep).
- Second injection: after 3-4 weeks.
  For a monovalent vaccine containing an inactivated Bluetongue Virus serotype 2 or 4, or for a bivalent vaccine containing both serotypes 2 and 4 together, one injection is sufficient.

In cattle:
- First injection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune cattle).
- Second injection: after 3-4 weeks.

- **Revaccination**

Annual.

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

Very rare and transient apathy can be observed after the administration of a double-dose of the vaccine. No other adverse events except those mentioned in section 3.6 were observed.

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, sell, supply and use this veterinary medicinal product containing serotypes 1, 2, 4 and 8 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 (sheep) and QI02AA08 (cattle)

To stimulate active immunity against bluetongue virus in the vaccinated animal.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of monovalent or bivalent formulation with Bluetongue Virus serotypes 1, 8 (100 ml, 50 ml and 10 ml bottles) and/or 2, 4 (100 ml and 50 ml bottles): 2 years.
Shelf life of monovalent or bivalent formulation with Bluetongue Virus serotypes 2 and/or 4 (10 ml bottles): 18 months.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Polypropylene bottle of 50 or 100 ml with butyl elastomer closure.
Box of 1 bottle of 100 doses (1 x 100 ml)
Box of 10 bottles of 100 doses (10 x 100 ml)
Box of 1 bottle of 50 doses (1 x 50 ml)
Box of 10 bottles of 50 doses (10 x 50 ml)

Type I glass bottle of 10 ml with butyl elastomer closure.
Box of 1 bottle of 10 doses (1 x 10 ml)

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/113/001-050

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 17/12/2010

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

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENT OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Box of 1 bottle of 10 ml,
Box of 1 bottle of 50 ml,
Box of 10 bottles of 50 ml,
Box of 1 bottle of 100 ml,
Box of 10 bottles of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:
Active substances *:

Inactivated Bluetongue Virus ≥ strain specific pass level (log_{10} pixels) **
* maximum of two different inactivated bluetongue virus serotypes

(**)Strain-specific pass levels	(**) Antigen content (VP2 protein) by immuno-assay
BTV1	1.9 log10 pixels/mL
BTV2	1.82 log10 pixels/mL
BTV4	1.86 log10 pixels/mL
BTV8	2.12 log10 pixels/mL

A confirmatory final potency test by seroneutralisation in rats is conducted when a batch is released

3. PACKAGE SIZE

10 doses (10 ml)
50 doses (50 ml)
10 x 50 doses (10 x 50 ml)
100 doses (100 ml)
10 x 100 doses (10 x100 ml)

4. TARGET SPECIES

Sheep and cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {dd/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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/113/001-050

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:
Active substances *:

Inactivated Bluetongue Virus ≥ strain specific pass level (log_{10} pixels) **
* maximum of two different inactivated bluetongue virus serotypes

(**)Strain-specific pass levels	(**) Antigen content (VP2 protein) by immuno-assay
BTV1	1.9 log10 pixels/mL
BTV2	1.82 log10 pixels/mL
BTV4	1.86 log10 pixels/mL
BTV8	2.12 log10 pixels/mL

A confirmatory final potency test by seroneutralisation in rats is conducted when a batch is released

3. TARGET SPECIES

Sheep and cattle

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days

6. EXPIRY DATE

Exp. {dd/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

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 10 and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml dose*:

Inactivated BTV1	≥ 1.9 log10 pixels
Inactivated BTV2	≥ 1.82 log10 pixels
Inactivated BTV4	≥ 1.86 log10 pixels
Inactivated BTV8	≥ 2.12 log10 pixels

(*) maximum of two different inactivated bluetongue virus serotypes.

10 doses (10 ml)
50 doses (50 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

BTVPUR suspension for injection for sheep and cattle

2. Composition

Each dose of 1 ml contains:

Active substance*:

Inactivated Bluetongue Virus ≥ strain specific pass level (log_{10} pixels) **
* maximum of two different inactivated bluetongue virus serotypes

(**)Strain-specific pass levels	(**) Antigen content (VP2 protein) by immuno-assay
BTV1	1.9 log10 pixels/mL
BTV2	1.82 log10 pixels/mL
BTV4	1.86 log10 pixels/mL
BTV8	2.12 log10 pixels/mL

A confirmatory final potency test by seroneutralisation in rats is conducted when a batch is released.

Adjuvants:
Aluminium hydroxide (Al^{3+}) 2.7 mg
Saponin 30 HU**
(**)Haemolytic units

The type of strain(s) (two strains at most) 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.

Appearance: homogeneous milky white.

3. Target species

Sheep and cattle.

4. Indications for use

Active immunisation of sheep to prevent viraemia* and to reduce clinical signs caused by Bluetongue Virus Serotypes 1, 2, 4 and/or 8 (combination of maximum 2 serotypes).

Active immunisation of cattle to prevent viraemia* caused by bluetongue virus serotypes 1, 2, 4 and/or 8, and to reduce clinical signs caused by bluetongue virus serotypes 1, 4 and/or 8 (combination of maximum 2 serotypes).
*below the level of detection by the validated RT-PCR method at 3.68 log_{10} RNA copies/ml, indicating no infectious virus transmission.

Onset of immunity: 3 weeks (or 5 weeks in sheep for BTV2) after the primary vaccination course for BTV1, BTV2 (cattle), BTV-4 and BTV-8 serotypes.

Duration of immunity: 1 year after primary vaccination course.

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.
If used in other domestic and wild ruminant species that are considered at risk of infection, its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of animals prior to mass vaccination. The level of efficacy for other species may differ from that observed in sheep and cattle.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Fertility:
The safety and the efficacy of the vaccine have not been established in breeding males. In this category of animals the vaccine should be used only according to the benefit/risk assessment by the responsible veterinarian and/or national Competent Authorities on the current vaccination policies against Bluetongue Virus (BTV).

Interactions 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 decided on a case by case basis.

Overdose:
Very rare and transient apathy can be observed after the administration of a double-dose of the vaccine. No other adverse events except those mentioned in section "Adverse Events" were observed.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product containing serotypes 1, 2, 4 and 8 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 and cattle:

- **Very rare** (<1 animal / 10,000 animals treated, including isolated reports): Hypersensitivity reactions, injection site swelling[1] and elevated temperature[2]

[1]at most 32 cm² in cattle and 24 cm^2 in sheep, which becomes residual 35 days later (≤ 1 cm^2)
[2]not exceeding 1.7°C (with an average of 1.1 ºC), may occur within 24 hours after vaccination

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

Administer one dose of 1 ml subcutaneously according to the following vaccination scheme:

- **Primary vaccination**

In sheep

- 1st injection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune sheep).
- 2nd injection: after 3-4 weeks

For a monovalent vaccine containing an inactivated Bluetongue Virus serotypes 2 or 4, or for a bivalent vaccine containing both serotypes 2 and 4 together, one injection is sufficient.

In cattle

- 1st injection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune cattle).
- 2nd injection: after 3-4 weeks.

- **Revaccination**

Annual.

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. Avoid multiple vial broaching.

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.

Shelf life after first opening the immediate packaging: use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp.

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 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/2/10/113/001-050

Not all pack sizes may be marketed
Box of 1 bottle of 10 doses (1 x 10 ml)
Box of 1 bottle of 50 doses (1 x 50 ml)
Box of 10 bottles of 50 doses (10 x 50 ml)
Box of 1 bottle of 100 doses (1 x 100 ml)
Box of 10 bottles of 100 doses (10 x 100 ml)

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:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Boehringer Ingelheim Animal
Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
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United Kingdom (Northern Ireland)
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17. Other information

The vaccine stimulates active immunity against Bluetongue Virus in the vaccinated animal.