ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 8 Ovis suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:

Bluetongue virus, serotype 8, strain BTV-8/BEL2006/02, inactivated. RP* ≥ 1

*Relative Potency by a mice potency test compared to a reference vaccine that was shown efficacious in sheep.

Adjuvants:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.2 mg
Potassium chloride	
Potassium dihydrogen phosphate	
Disodium hydrogen phosphate dodecahydrate	
Sodium chloride	
Water for injections	

Off-white or pink suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

Active immunisation of sheep from 1.5 months of age for the prevention* of viraemia caused by Bluetongue virus, serotype 8.

*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome).

Onset of immunity: 25 days after completion of the primary vaccination scheme.
Duration of immunity: at least 1 year after completion of the primary vaccination scheme.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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]Not exceeding 1.2 °C, during the first 24 hours after vaccination.
[2]For not more than 7 days.
[3]Palpable nodules (subcutaneous granuloma), possibly persisting for more than 48 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 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.

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

Subcutaneous use.

Primary vaccination:
Administer one dose of 2 ml according to the following vaccination scheme:

1st dose: from 1.5 months of age.
2nd dose: after 3 weeks.

Re-vaccination:
Any re-vaccination scheme should be agreed by the competent authority or by the responsible veterinarian, taking into account the local epidemiological situation.

Method of 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.

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

A transient increase in rectal temperature, not exceeding 0.6 °C, may occur during the 24 hours following administration of a 2-fold overdose.

Administration of a 2-fold overdose may be followed in most animals by a local reaction at the injection site. These reactions take the form in most cases of a general swelling of the injection site (persisting for not more than 9 days) or of palpable nodules (subcutaneous granuloma, possibly persisting for more than 63 days).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QI04AA02

To stimulate active immunity against Bluetongue virus, serotype 8 in sheep.

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.
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

Type II hydrolytic glass bottles containing 100 or 240 ml. The glass bottle is closed with butyl stopper and held in place with an aluminium cap.

Pack sizes:
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.

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/2/09/104/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 15/01/2010.

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 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 (100 ML OR 240 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 8 Ovis Suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Bluetongue virus, serotype 8, strain BTV-8/BEL2006/02, inactivated.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods: 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/2/09/104/001 (100 ml)
EU/2/09/104/002 (240 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

GLASS BOTTLE (100 ML OR 240 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 8 Ovis Suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Bluetongue virus, serotype 8, strain BTV-8/BEL2006/02, inactivated.

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

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: 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}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zulvac 8 Ovis suspension for injection for sheep

2. Composition

Each dose of 2 ml contains:

Active substances:
Bluetongue virus, serotype 8, strain BTV-8/BEL2006/02, inactivated. RP* ≥ 1

*Relative Potency by a mice potency test compared to a reference vaccine that was shown efficacious in sheep.

Adjuvants:

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

Excipients:

Thiomersal	0.2 mg

Off-white or pink suspension.

3. Target species

Sheep.

4. Indications for use

Active immunisation of sheep from 1.5 months of age for the prevention* of viraemia caused by Bluetongue virus, serotype 8.

*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome).

Onset of immunity: 25 days after completion of the primary vaccination scheme.
Duration of immunity: at least 1 year after completion of the primary vaccination scheme.

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.

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.

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 Eon 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:
A transient increase in rectal temperature, not exceeding 0.6 °C, may occur during the 24 hours following administration of a 2-fold overdose.
Administration of a 2-fold overdose may be followed in most animals by a local reaction at the injection site. These reactions take the form in most cases of a general swelling of the injection site (persisting for not more than 9 days) or of palpable nodules (subcutaneous granuloma possibly persisting for more than 63 days).

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]Not exceeding 1.2 °C, during the first 24 hours after vaccination.
[2]For not more than 7 days.
[3]Palpable nodules (subcutaneous granuloma), possibly persisting for more than 48 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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Subcutaneous use.

Primary vaccination:
Administer one dose of 2 ml according to the following vaccination scheme:
1st dose: from 1.5 months of age.
2nd dose: after 3 weeks.

Re-vaccination:
Any re-vaccination scheme should be agreed by the competent authority or by the responsible veterinarian, taking into account the local epidemiological situation.

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/2/09/104/001-002

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.

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 and contact details to report suspected adverse events:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

België/Belgique/Belgien
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pharmvig-belux@zoetis.com

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Manufacturer responsible for batch release:
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Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

17. Other information

To stimulate active immunity against Bluetongue virus, serotype 8 in sheep.