

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

One dose of 2 ml of vaccine contains:

Active substance(s):

Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02 RP* \geq 1

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

Adjuvant(s):

Aluminium hydroxide (Al³⁺) 4 mg
Saponin 0.4 mg

Excipient(s):

Thiomersal 0.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Off-white or pink suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the 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) \geq 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 25 days after administration of the second dose.
The duration of immunity is at least 1 year after the primary vaccination course.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Use in other domestic and wild ruminant species that are considered at risk of infection 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.

No information is available on the use of the vaccine in seropositive animals including those with maternally derived antibodies.

4.5 Special precautions for use

Special precautions for use in animals

Only use in healthy animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

In one laboratory safety study, transient increase in rectal temperature during the 24 hours following vaccination not exceeding 1.2°C and local reaction at the injection site, in most cases in the form of a general swelling (persisting for not more than 7 days) or of palpable nodules (subcutaneous granuloma, possibly persisting for more than 48 days) were observed very commonly. These clinical signs have been reported very rarely from the field.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

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 BTV.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

Subcutaneous use.

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.

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.

Primary vaccination:

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

1st injection: from 1.5 months of age.

2nd injection: after 3 weeks.

Revaccination:

As the duration of immunity is not yet fully established, any revaccination scheme should be agreed by the Competent Authority or by the responsible veterinarian, taking into account the local epidemiological situation.

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

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

Administration of a two-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).

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines – bluetongue virus vaccine.
ATC vet code: QI04AA02

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

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Aluminium hydroxide
Saponin
Thiomersal
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate dodecahydrate
Sodium chloride
Water for injections

6.2 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).
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Type II glass bottle with butyl elastomer closure.

Pack sizes

Pack of 1 bottle of 50 doses (100 ml).

Pack of 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/2/09/104/001

EU/2/09/104/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15/01/2010

Date of last renewal: 07/11/2014

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

The manufacture, import, possession, sale, supply and/or use of ZULVAC 8 Ovis may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use ZULVAC 8 Ovis must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

ANNEX II

- A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) 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(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)

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

Name and address of the manufacturer(s) responsible for batch release

Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón 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 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 are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

The periodic safety update report (PSUR) cycle should be restarted for submission of 6 monthly reports (covering all authorised presentations of the product) for the next two years, followed by yearly reports for the subsequent two years and thereafter at 3 yearly intervals, unless otherwise required.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box 1 x 100ml / Carton box 1 x 240 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZULVAC 8 Ovis suspension for injection for sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 2 ml contains:
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02

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

For subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: 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. SPECIFIC 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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in Member States on the Whole or part of its territory. See package leaflet for further information

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/2/09/104/001

EU/2/09/104/002

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial label 100 ml / Vial label 240 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZULVAC 8 Ovis suspension for injection for sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 2 ml contains:
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02

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

For subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: 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. SPECIFIC 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”

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)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

**PACKAGE LEAFLET FOR:
ZULVAC 8 Ovis suspension for injection for sheep**

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

Marketing authorisation holder

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

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZULVAC 8 Ovis suspension for injection for sheep

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

One dose of 2 ml of vaccine contains:

Active substance:

Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02 RP* \geq 1

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

Adjuvant:

Aluminium hydroxide (Al ³⁺)	4 mg
Saponin	0.4 mg

Excipient:

Thiomersal	0.2 mg
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4. INDICATION(S)

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

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

Onset of immunity: 25 days after administration of the second dose.
The duration of immunity is at least 1 year after the primary vaccination course.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In one laboratory safety study, transient increase in rectal temperature during the 24 hours following vaccination not exceeding 1.2°C and local reaction at the injection site, in most cases in the form of a general swelling (persisting for not more than 7 days) or of palpable nodules (subcutaneous granuloma, possibly persisting for more than 48 days) were observed very commonly. These clinical signs have been reported very rarely from the field.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous use.

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.

Primary vaccination:

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

1st injection: from 1.5 months of age.

2nd injection: after 3 weeks.

Revaccination:

As the duration of immunity is not yet fully established, any revaccination 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

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 PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Protect from light.

Do not freeze.

Once broached use immediately.

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

12. SPECIAL WARNING(S)

Special warnings for each target species:

Use in other domestic and wild ruminant species that are considered at risk of infection 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.

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:

Only use in healthy animals.

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 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.

Incompatibilities

Do not mix with any other veterinary medicinal product.

Overdose:

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

Administration of a two-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).

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

Pack sizes

Pack of 1 bottle of 50 doses (100 ml).

Pack of 1 bottle of 120 doses (240 ml).

Not all pack sizes may be marketed.

The manufacture, import, possession, sale, supply and/or use of ZULVAC 8 Ovis may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use ZULVAC 8 Ovis must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

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

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