

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARDBOARD BOX (20 ML, 100 ML OR 240 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 1+8 Ovis Suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:

Bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1, inactivated
Bluetongue virus, serotype 8, strain BTV-8/BEL2006/02, inactivated

3. PACKAGE SIZE

20 ml (10 doses)
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 UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5089

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE VIAL (100 ML and 240 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 1+8 Ovis Suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:

Bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1, inactivated
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 UK Limited

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGING UNITS
VIAL (20 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 1+8 Ovis

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1, inactivated
Bluetongue virus, serotype 8, strain BTV-8/BEL2006/02, inactivated

20 ml (10 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zulvac 1+8 Ovis suspension for injection for sheep

2. Composition

Each dose of 2 ml contains:

Active substances:

Bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1, inactivated RP* ≥ 1
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	4 mg (Al ³⁺)
Saponin	0.4 mg

Excipients:

Thiomersal	0.2 mg
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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, serotypes 1 and 8.

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

Onset of immunity: 3 weeks.

Duration of immunity: 1 year.

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:

Not applicable.

Pregnancy:

Can be used during pregnancy.

Lactation:

The safety of the vaccine has not been established during 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).

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 products.

7. Adverse events

Sheep:

Very common (>1 animal / 10 animals treated):
Injection site swelling ¹ Injection site nodule ²
Common (1 to 10 animals / 100 animals treated):
Elevated temperature ³

¹General swelling, for up to 7 days.

²Palpable nodules (subcutaneous granuloma), may persist for more than 48 days.

³Transient, up to 1.2 °C, for up to 24 hours.

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:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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.

Revaccination:

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

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

Vm 42058/5089

Cardboard box with 1 vial of 10 doses (20 ml).
Cardboard box with 1 vial of 50 doses (100 ml).
Cardboard box with 1 vial of 120 doses (240 ml).

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
UK
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:

Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

17. Other information

To stimulate active immunity against Bluetongue virus, serotypes 1 and 8 in sheep.

POM-V

Gavin Hall

Approved: 02 December 2025