SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac 1+8 Ovis suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:
Bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1, inactivatedRP* ≥ 1
Bluetongue virus, serotype 8, strain BTV-8/BEL2006/02, inactivatedRP* ≥ 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:

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, 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 after completion of the primary vaccination scheme.
Duration of immunity: 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
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 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]

[1]General swelling, for up to 7 days.
[2]Palpable nodules (subcutaneous granuloma), may persist for more than 48 days.
[3]Transient, up to 1.2 °C, for up to 24 hours.

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.

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).

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.

Revaccination:
Any revaccination 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 vial 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, serotypes 1 and 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

High density polyethylene (HDPE) vials of 20, 100 or 240 ml with chlorobutyl elastomer stopper and aluminium seal containing 10, 50 or 120 doses of vaccine.

Pack sizes:
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.

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

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5089

8. DATE OF FIRST AUTHORISATION

14 March 2011.

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

September 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 02 December 2025