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:
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02 RP* ≥ 1

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

Adjuvant(s):

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

Excipient:

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) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome).

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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

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.

4.6 Adverse reactions (frequency and seriousness)

A 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 in one laboratory safety study. 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 treated displaying adverse reaction(s))-common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 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 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. 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.

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.

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: Immunologicals for Ovidae, inactivated viral vaccines for sheep, bluetongue virus.
ATCvet code: QI04AA02.
To stimulate active immunity against bluetongue virus, serotype 8 in sheep.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Quil A (*Quillaja saponaria* saponin extract)
Thiomersal
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate dodecahydrate
Sodium chloride
Water for injections

6.2 Major 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 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
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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5090

9. DATE OF FIRST AUTHORISATION

15 January 2010

10. DATE OF REVISION OF THE TEXT

May 2021

Approved 17 May 2021