SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac BTV suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances: One of the following inactivated bluetongue virus strains	**Amount per 2 ml dose** (BTV-1, BTV-4, BTV-8 in sheep; BTV-1, BTV-8 in cattle)	**Amount per 4 ml dose** (BTV-4 in cattle)
Inactivated bluetongue virus, serotype 1, strain BTV-1/ALG2006/01 E1	RP* ≥ 1	n.a.
Inactivated bluetongue virus, serotype 8, strain BTV-8/BEL2006/02	RP* ≥ 1	n.a.
Inactivated bluetongue virus, serotype 4, strain SPA-1/2004	RP* ≥ 0.8	RP* ≥ 0.8
Adjuvants:		
Al^{3+} (as hydroxide)	4 mg	8 mg
Quil-A (*Quillaja saponaria* saponin extract)	0.4 mg	0.8 mg
Excipients:		
Thiomersal	0.2 mg	0.4 mg
For the full list of excipients, see section 6.1.		

n.a.: not applicable

*Relative potency by a mice potency test compared to a reference vaccine efficacious in sheep and/or cattle.

The type of strain included in the final product will be adapted to the current epidemiological situation at the time of formulation of the final product and will be shown on the label. The target species will also be shown on the label.

3. PHARMACEUTICAL FORM

Suspension for injection.
Off-white or pink liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle

4.2 Indications for use, specifying the target species

Sheep:
Active immunisation of sheep from 6 weeks of age for the prevention* of viraemia caused by bluetongue virus, serotype 1 or serotype 8.

Active immunisation of sheep from 6 weeks of age for the reduction* of viraemia caused by bluetongue virus, serotype 4.

*Below the level of detection of < 3.9 $\log_{10}$ genome copies/ml by the validated RT-qPCR method, indicating no presence of viral genome.

Onset of immunity: 21 days after completion of the primary vaccination scheme.
Duration of immunity: 12 months after completion of the primary vaccination scheme.

Cattle:
Active immunisation of cattle from 12 weeks of age for the prevention** of viraemia caused by bluetongue virus, serotype 1, serotype 4 or serotype 8.

**Below the level of detection of < 3.4 $\log_{10}$ genome copies/ml by a validated RT-qPCR method, indicating no presence of viral genome.

Onset of immunity:
Bluetongue virus, serotype 1: 15 days after completion of the primary vaccination scheme.
Bluetongue virus, serotype 8: 25 days after completion of the primary vaccination scheme.
Bluetongue virus, serotype 4: 14 days after completion of the primary vaccination scheme.

Duration of immunity:
Bluetongue virus, serotype 1: 12 months after completion of the primary vaccination scheme.
Bluetongue virus, serotype 8: 12 months after completion of the primary vaccination scheme.
Bluetongue virus, serotype 4: 6 months after completion of the primary vaccination scheme.

There is evidence of BTV-1 seroneutralising antibodies indicative of protection for up to 21 months after primary vaccination

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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

If used in other domestic and wild ruminant species that are considered at risk of infection, its use in these species 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 and cattle.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Sheep:
A transient increase in rectal temperature, not exceeding 1.6 °C, may very commonly occur during the 48 hours following vaccination.
A local reaction at the injection site may occur very commonly after vaccination. These reactions take the form in most cases of a diffuse swelling of the injection site (persisting for not more than 7 days) or of palpable nodules up to a size of 60 cm^2 (subcutaneous granuloma, decreasing in size over time but possibly persisting for more than 50 days).

Cattle administered a 2 ml dose:
A transient increase in rectal temperature, not exceeding 2.7 °C, was commonly observed during the 48 hours following vaccination in field safety studies.
Local reactions of < 2 cm diameter were very commonly observed while reactions of up to 5 cm diameter were commonly observed after administration of a single dose in field safety studies. These resolved within a maximum of 25 days. Local reactions may increase slightly following the second dose, in this case lasting up to 15 days. Local reactions of up to 5 cm diameter were very commonly observed and reactions > 5 cm diameter were commonly observed after repeated administration of a single dose in field safety studies.

Cattle administered a 4 ml dose:
A transient increase in rectal temperature, not exceeding 2.7 °C, was very commonly observed within 48 hours following vaccination in the lab and field safety study conducted. The pyrexia observed had a maximum duration of 2 days. Local reactions at the injection site of up to 6 cm in diameter, which resolved in a maximum of 8 days, also very commonly appeared in the lab safety study conducted.

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 in sheep and cattle.

Lactation:
The safety of the vaccine has not been established during lactation in sheep. It can be used during lactation in cattle.

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).

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

Sheep:

Subcutaneous use.

Primary vaccination
Administer one dose of 2 ml according to the following vaccination scheme:
1st injection: from 6 weeks of age.
2nd injection: after 3 weeks.

Revaccination
For protection against serotype 1 or serotype 8, administer one dose of 2 ml, every 12 months.
For protection against serotype 4, administer two doses of 2 ml three weeks apart, every 12 months.

Cattle:

Intramuscular use.

For protection against serotype 1 and serotype 8:

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

1st injection: from 12 weeks of age.
2nd injection: after 3 weeks.

Revaccination
For protection against serotype 1, administer one dose of 2 ml, every 12 months.
For protection against serotype 8, administer two doses of 2 ml three weeks apart, every 12 months.

For protection against serotype 4:

Primary vaccination
Administer a dose of 4 ml according to the following vaccination scheme:
1st injection: from 12 weeks of age.
2nd injection: after 3 weeks.

Revaccination
Administer two doses of 4 ml three weeks apart, every 6 months

Method of administration (sheep and cattle)
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 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.

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

Sheep:

After administration with a two-fold overdose (4 ml), reactions in sheep are similar to those seen after administration of a single dose, but injection site reactions may persist for a longer time (general swelling at the injection site persisting for not more than 9 days or subcutaneous granuloma possibly persisting for more than 63 days).

Cattle:

A transient increase in rectal temperature, not exceeding 2 °C, may occur in 10% of the animals during the 24 hours following administration of a two-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Bovidae, inactivated viral vaccines for cattle.
ATCvet code:QI02AA08 - bluetongue virus.
To stimulate active immunity of sheep and cattle against bluetongue virus serotype(s) related to those contained in the vaccine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Quil-A (*Quillaja saponaria* saponin extract)
Thiomersal
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
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 (Bluetongue virus, serotype 1 and serotype 8) or 18 months (Bluetongue virus, serotype 4).
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles of 20, 100 or 240 ml with chlorobutyl elastomer stopper and aluminium seal.

Pack sizes:
Cardboard box with 1 bottle of 10 doses of 2 ml or 5 doses of 4 ml (20 ml).
Cardboard box with 1 bottle of 50 doses of 2 ml or 25 doses of 4 ml (100 ml).
Cardboard box with 1 bottle of 120 doses of 2 ml or 60 doses of 4 ml (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

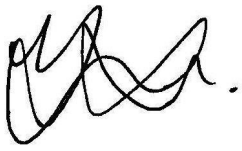
Vm 42058/5091

9. DATE OF FIRST AUTHORISATION

25 January 2017

10. DATE OF REVISION OF THE TEXT

May 2022



Approved: 05 May 2022