

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zulvac SBV suspension for injection for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:	Each dose of 2 ml (cattle) contains	Each dose of 1 ml (sheep) contains
Schmallenberg virus, strain BH80/11-4, inactivated.	RP* \geq 1	RP* \geq 1

*Relative potency (mice potency test) compared to a reference vaccine that was shown efficacious in the target animal species.

Adjuvants:

Aluminium hydroxide	385.2 mg (4 mg Al ³⁺)	192.6 mg (2 mg Al ³⁺)
Quil-A (<i>Quillaja saponaria</i> saponin extract)	0.4 mg	0.2 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product	
	Each dose of 2 ml (cattle) contains	Each dose of 1 ml (sheep) contains
Thiomersal	0.2 mg	0.1 mg
Potassium chloride		
Potassium dihydrogen phosphate		
Disodium phosphate dihydrate		
Sodium chloride		
Water for injections		

Off-white or pink suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

Cattle:

For active immunisation of cattle from 3.5 months of age to reduce viraemia* associated with infection by Schmallerberg virus.

Onset of immunity: 2 weeks after completion of the primary vaccination scheme.

Duration of immunity: 1 year after completion of the primary vaccination scheme.

Sheep:

For active immunisation of sheep from 3.5 months of age to reduce viraemia* associated with infection by Schmallerberg virus.

Onset of immunity: 3 weeks after vaccination.

Duration of immunity: 6 months after vaccination.

Vaccination of breeding sheep before pregnancy according to the recommended schedule described in section 3.9 results in reduction of viraemia* and transplacental infection associated with infection by Schmallerberg virus during the first trimester of pregnancy.

*Below the level of detection by the validated RT-PCR method at 3.6 log₁₀ RNA copies/ml of plasma for cattle and at 3.4 log₁₀ RNA copies/ml of plasma for sheep.

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:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Elevated temperature ¹ Injection site granuloma ²
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¹Transient, up to 1.5 °C, for up to 2 days.

²Intramuscular, up to 0.7 cm in diameter, for up to 10 days.

Sheep:

Very common (>1 animal / 10 animals treated):	Elevated temperature ¹ Injection site swelling ² Injection site granuloma ²
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¹Transient, up to 1.5 °C, for up to 24 hours.

²Diffuse swelling or subcutaneous granulomas up to 8 cm in diameter. The reactions may be observed for at least 47 days in the form of diffuse swelling of less than 2 cm diameter.

Pregnant ewe:

Very common (>1 animal / 10 animals treated):	Elevated temperature ¹ Injection site swelling ² Injection site granuloma ²
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¹Transient, up to 0.8 °C, for up to 4 hours.

²Diffuse swelling or subcutaneous granulomas up to 8 cm diameter. The reactions may be observed for at least 97 days in the form of small granulomas of less than 0.5 cm in diameter.

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:

Sheep: Can be used at 2 months of pregnancy and onwards.

Cattle: The safety and efficacy of the vaccine have not been established in pregnant cattle.

Lactation:

The safety and the efficacy of the vaccine have not been established in lactating animals.

Fertility:

The safety and the efficacy of the vaccine have not been established in breeding males.

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

Shake the vial before use.

Cattle:

Intramuscular use (in the neck).

Primary vaccination:

For cattle from 3.5 months of age: administer two doses of 2 ml three weeks apart.

Booster vaccination:

Administer two doses of 2 ml three weeks apart, every year.

Sheep:

Subcutaneous use (in the axillar region behind the elbow).

Primary vaccination:

For sheep from 3.5 months of age: administer one dose of 1 ml.

For female sheep at breeding age: administer one dose of 1 ml at least 14 days prior to breeding.

Booster vaccination:

For non-breeding sheep: administer one dose of 1 ml, every 6 months.

For female breeding sheep: administer one dose of 1 ml at least 14 days prior to every breeding.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AA

To stimulate active immunity against Schmallenberg virus in cattle and 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

Cardboard box with 1 high density polyethylene (HDPE) vial with chlorobutyl stopper and aluminium seal, containing 50 ml of vaccine.

Cattle: Cardboard box with 1 vial of 50 ml (25 doses).
Sheep: Cardboard box with 1 vial of 50 ml (50 doses).

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 42058/5092

8. DATE OF FIRST AUTHORISATION

6 February 2015

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: 27 March 2026