



Schmallenberg Virus

Just because you haven't seen it,
doesn't mean it isn't there.



Bovilis[®] SBV

The world's first Schmallenberg vaccine

Use Medicines Responsibly.

Please see: www.noah.co.uk/responsible for more information.

Presentation; Bovilis SBV is an Inactivated Schmallenberg virus vaccine (SBV) inducing at least 5.0 log₂ VN titre¹

Uses; Cattle: For the active immunisation of cattle to prevent viraemia caused by Schmallenberg virus. Sheep: For the active immunisation of sheep to reduce viraemia caused by Schmallenberg virus.

Onset of immunity; 3 weeks after vaccination.

Duration of immunity; unknown. This is a Provisional Marketing Authorisation. A full set of supporting efficacy data is not available for this product.

Dosage and administration; Before using the vaccine allow it to reach ambient temperature (15 - 25°C). Shake the bottle before use and periodically during use. Use clean and sterile vaccination equipment and avoid the introduction of contamination. It is recommended to use a multiject vaccination system.

Cattle: Primary vaccination: Cattle from 2 months of age: intramuscular injection of two doses of 2 ml, administered with an interval of approximately 4 weeks. Revaccination: As the duration of immunity is not yet established, any revaccination scheme should be agreed by the Competent Authority or by the responsible veterinarian, taking into account the local epidemiological situation.

Sheep: Primary vaccination: Sheep from 4 months of age: subcutaneous injection of one dose of 2 ml. Revaccination: As the duration of immunity is not yet established, any revaccination scheme should be agreed by the Competent Authority or by the responsible veterinarian, taking into account the local epidemiological situation.

Contra-indications, warnings, etc;

Contraindications: None.

Special warnings: This vaccine has been evaluated for safety and efficacy in sheep and cattle. 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. No information is available on the use of the vaccine in seropositive animals, including those with maternally derived antibodies.

Special precautions for use;

Special precautions for use in animals: Vaccinate only healthy animals.

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.

Adverse reactions (frequency and seriousness); Immunisation may result in a slight rise in temperature (up to about 1°C) for up to three days after vaccination, and temporary swellings at the injection site. In sheep, swellings may be observed in most of the vaccinated animals. In sheep, swellings have been observed up to 9 cm² (average 7.5 cm²), which may last for more than two weeks. No local reactions have been observed in cattle. As with any other vaccine, occasional hypersensitivity reactions may occur.

Use during pregnancy, lactation or lay; Do not use in pregnant animals. The safety and efficacy of the vaccine has not been established in breeding males. In these categories of animals the vaccine should be used only according to the risk/benefit assessment by the responsible veterinarian and/or the national Competent Authorities, depending on the current vaccination policies against SBV.

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.

Withdrawal period; Zero days.

Special precautions for storage; Store and transport refrigerated (2 - 8°C). Protect from direct light. Do not freeze.

Shelf life after first opening the immediate packaging; use immediately after broaching (maximum within 4 hours).

Legal category **POM-V**

Reference:

1. Akabane Virus, The Center for Food Security and Public Health, Iowa State University, April 2009.

Further information is available from MSD Animal Health, Walton Manor, Walton,

Milton Keynes MK7 7AJ. Tel: 01908 685685 Fax: 01908 685555

E: vet-support.uk@merck.com Internet: www.msd-animal-health.co.uk



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Schmallenberg Virus & Bovilis SBV Your Questions Answered

RU-E01524 76891 • JUNE 2013/MP/10K



Schmallenberg Virus – Your Questions Answered

What is Schmallenberg (SBV) virus?

SBV is a new Orthobunyavirus in the Simbu serogroup and is closely related to Shamonda virus. The Orthobunyavirus genus is prevalent primarily in Africa, Australia and Oceania but has not previously been identified in Europe. Nearly all species of Orthobunyavirus are transmitted by biting insect vectors including midges.

How much of a threat is SBV to UK ruminant livestock?

SBV is a highly significant threat on the majority of UK cattle and sheep farms because infected midges have ranged far and wide. The disease has spread very rapidly because plumes of midges carry a heavy viral load. Cases are being identified further and further north. In fact, even ruminant livestock in Scandinavia have now been infected.

What are the clinical signs of Schmallenberg?

Pregnant ruminant livestock are the most vulnerable and it is their unborn foetuses that bear the brunt of the worst effects of the disease. The peak risk period for foetal deformities in sheep is the first 28-60 days of pregnancy, while cattle is between 80-140 days of pregnancy. It is believed that infections before these periods may cause foetal death and abortion, but as yet there is no research data available to confirm these anecdotal reports from the field.

Peak risk periods during gestation¹



How long does immunity last following natural infection?

The duration of immunity following natural infection is not yet fully understood. It was hoped that once the virus had passed through a herd or flock then animals would have a good level of immunity for subsequent breeding seasons. Anecdotal evidence from mainland Europe shows strong protective immunity following natural exposure to the virus, but no trials have yet been done to establish the duration of this immunity. Most experts expect it to last for at least 12 months, which corresponds to the timeframe scientists have been studying this new virus, but nobody really knows.

What is the within flock/herd prevalence following natural infection?

This is unclear because midge populations, weather conditions and animal breeding seasons vary so much across the UK. In a letter to the Veterinary Record, only 25% of housed cattle in a herd showed evidence of infection, yet only 7 miles away another dairy herd grazing outside during the summer showed 75% of the cows being infected. In another sero-prevalence study with sheep it was also demonstrated that individual animal exposure to SBV in disease positive flocks is very variable. Even in high SBV risk areas the work showed that the proportion of susceptible animals was greater than the protected ones.

Bovilis SBV – Your Questions Answered

What is Bovilis SBV?

Bovilis SBV is the first and only vaccine against Schmallenberg virus and is the result of a highly concentrated effort to bring a SBV vaccine to the market.

What type of vaccine is Bovilis SBV?

Bovilis SBV contains inactivated Schmallenberg virus plus adjuvants to stimulate the immune response.

What is Bovilis SBV licenced for?

Bovilis SBV is indicated for the active immunisation of cattle to prevent viraemia against SBV and for the active immunisation of sheep to reduce viraemia against SBV.

What is the vaccine regime in cattle?

Healthy, non pregnant females can be vaccinated intra-muscularly from two months of age. The primary vaccination course requires two 2ml doses to be given approximately four weeks apart.

What is the vaccine regime in sheep?

Non-pregnant, healthy ewes can be vaccinated sub-cutaneously from four months of age. Sheep only need a single 2ml dose.

What is the onset of immunity and duration of immunity/booster requirements?

Onset of immunity is three weeks after vaccination. Duration of immunity is not yet established.

When should I vaccinate with Bovilis SBV?

It is recommended the vaccination course is completed at least three weeks before mating in order to ensure the animal has been actively immunised before gestation starts

Bovilis SBV is available in which pack sizes?

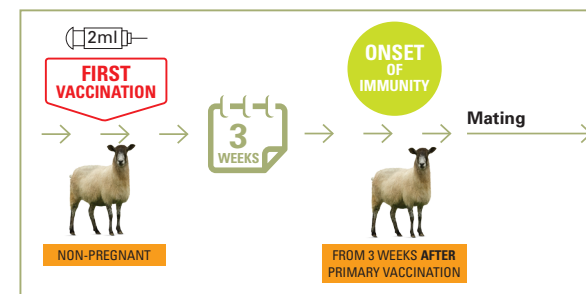
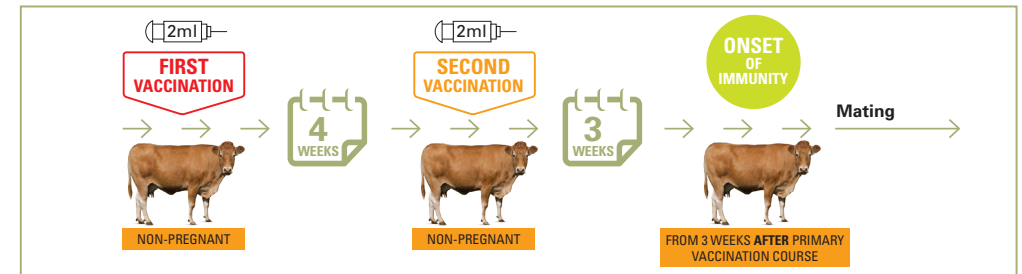
Bovilis SBV is available in 100ml and 20ml (PET) vials.

What type of vaccinator should I use to vaccinate my livestock with Bovilis SBV?

There is a specific Bovilis SBV vaccinator, which is bottle mounted and contains both Sterimatic kits for cattle and sheep. The vaccinators are available from your veterinary surgeon.



Vaccination Schedules – Cattle and sheep



Species	Dose	Injection	Schedule
Cattle	2 ml	IM	2 injections 4 weeks apart
Sheep	2 ml	SC	1 injection