SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SBVvax, suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml of vaccine contains:

Active substances:
Schmallenberg virus antigen $\geq$ 6.3 $CCID_{50}$*
(*) equivalent to titre prior to inactivation (log10)

Adjuvants:

Aluminium hydroxide	2.7 mg
Saponin	30 HU**

(**) Haemolytic units

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Milky white suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle

4.2 Indications for use, specifying the target species

Active immunisation of sheep and cattle to prevent viraemia* caused by Schmallenberg virus.
* (below the level of detection by the validated qRT-PCR method at 3.2 log10 RNA copies/ml)

Onset of immunity has been demonstrated 3 weeks after the primary vaccination course.
The duration of immunity has not been established.
This is a Provisional Marketing Authorisation. A full set of supporting efficacy data is not available for this product.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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 safety and efficacy of the vaccine in seropositive animals, including those with maternally derived antibodies.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate healthy animals only.

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)

In cattle, injection of a double dose of vaccine may be followed by a transient local swelling at the injection site (at most 12cm, reducing to 4cm within 14 days). Local reactions progressively evolve into small nodules, at most 2cm in diameter observed for at least 42 days post vaccination.
A transient increase in body temperature, normally not exceeding an average of 1.3 °C, may occur within 24-48 hours after vaccination.
In sheep, injection of a double dose of vaccine may be followed by a transient local swelling at the injection site (at most 6 cm, reducing to 3 cm within 14 days). Local reactions progressively evolve into small nodules, at most 2cm in diameter observed for at least 42 days post vaccination.
A transient increase in body temperature, normally not exceeding an average of 1.4 °C, may occur within 24-48 hours after vaccination.

4.7 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.
It is advisable to vaccinate females at least 1 month before insemination or mating.

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 decided on a case by case basis.

4.9 Amounts to be administered and administration route

Apply usual aseptic procedures.
Shake gently immediately before use. Avoid bubble formation, as this can be irritating at the site of injection. The entire contents of the bottle should be used immediately after broaching and during the same procedure. Avoid multiple broaching of the bottle.
Administer one dose of 1 ml subcutaneously according to the following vaccination scheme:

- **Primary vaccination**

In sheep
- One injection of 1-ml dose: from 2.5 months of age.

In cattle
- 1st injection of 1-ml dose: from 2.5 months of age
- 2nd injection of 1-ml dose: 3 weeks after the 1st injection.

- **Revaccination**

As the duration of immunity is not yet fully established in cattle or sheep, any revaccination 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

In cattle, injection of a double dose of vaccine containing 4 times the antigen payload of the standard vaccine, may be followed by a transient local swelling at the injection site (at most 12cm, reducing to 4cm within 14 days). Local reactions progressively evolve into small nodules, at most 2cm in diameter observed for at least 42 days post vaccination.
A transient increase in body temperature, normally not exceeding an average of 1.3 °C, may occur within 24-48 hours after vaccination.

In sheep, injection of a double dose of vaccine containing 4 times the antigen payload of a standard vaccine, may be followed by a transient local swelling at the injection site (at most 6 cm, reducing to 3 cm within 14 days). Local reactions progressively evolve into small nodules, at most 2cm in diameter observed for at least 42 days post vaccination.
A transient increase in body temperature, normally not exceeding an average of 1.4 °C, may occur within 24-48 hours after vaccination.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines, ATCvet code: QI04AA (sheep).

The vaccine contains inactivated Schmallenberg virus with aluminium hydroxide and saponin adjuvants. It induces active immunity against Schmallenberg virus in the vaccinated animal.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Purified saponin
Phosphate buffer
Glycine buffer
Water for injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Provisional shelf life of the veterinary medicinal product as packaged for sale: 1 year.
Shelf life after first opening the immediate packaging: immediately after broaching.

6.4 Special precautions for storage

Store and transport refrigerated (2^0C- 8^0C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Polypropylene bottle of 50 ml with butyl elastomere closure.
Box of 1 bottle of 50 doses (1 x 50 ml).
Box of 10 bottles of 50 doses (10 x 50 ml).
Polypropylene bottle of 200 ml with butyl elastomere closure.
Box of 1 bottle of 200 doses (1 x 200ml).

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4256

9. DATE OF FIRST AUTHORISATION

27 November 2013

10. DATE OF REVISION OF THE TEXT

November 2018

ADDITIONAL INFORMATION

All suspected adverse reactions and any suspected lack of efficacy should be reported to 01344 746957 at Boehringer Ingelheim Animal Health UK Ltd., Ellesfield Avenue, Bracknell, Berkshire RG12 8YS.

Approved 29 November 2018