PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SBVvax, suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Schmallenberg virus antigen ≥ 6.3 $CCID_{50}$*
(*) equivalent to titre prior to inactivation (log10)

3. PHARMACEUTICAL FORM

Milky white suspension for injection.

4. PACKAGE SIZE

1 x 50 doses

5. TARGET SPECIES

Sheep and cattle.

6. INDICATION(S)

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.)

7. METHOD AND ROUTES OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C-8°C).
Do not freeze.

Protect from light.
Once broached use immediately.

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4256

17. MANUFACTURER'S BATCH NUMBER

Lot:

18. ADDITIONAL INFORMATION

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (Label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SBVvax, suspension for injection

2. QUANTITY OF THE ACTIVE SUBSTANCES

1 ml/dose

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 doses

4. ROUTE OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. ADDITIONAL INFORMATION

Sheep – Cattle

Read the package leaflet before use.

Once broached use immediately.

Vm 08327/4256

Boehringer Ingelheim Animal Health UK Ltd

POM-V

PACKAGE LEAFLET FOR: SBVvax, suspension for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK
Manufacturer responsible for batch release:
MERIAL, Lyon Porte des Alpes
Rue de l'Aviation 69800 Saint Priest - France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SBVvax Suspension for injection

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each dose of 1 ml of vaccine contains:
Active substances:
Schmallenberg virus antigen..... ≥ 6.3 $CCID_{50}$*
(*) equivalent to titre prior to inactivation (log 10)

Adjuvants:
Aluminium
hydroxide..... 2.7 mg
Saponin ..... 30 HU**
(**) Haemolytic units

Milky white suspension for injection.

4. INDICATION

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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 6cm, reducing to 3cm 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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep and cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Subcutaneous use.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2°-8°C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf life after first opening the immediate packaging: immediately after broaching.

12. SPECIAL WARNING(S)

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 use of the vaccine in seropositive animals, including those with maternally derived antibodies.

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.

Pregnancy/Fertility:
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.

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.

Overdose (symptoms, emergency procedures, antidotes):
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 6cm, reducing to 3cm 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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Polypropylene bottle of 50ml with butyl elastomere closure.
Box of 1 bottle of 50 doses (1 x 50ml)
Box of 10 bottles of 50 doses (10 x 50ml)
Polypropylene bottle of 200ml with butyl elastomere closure
Box of 1 bottle of 200 doses (1 x 200ml)
Not all pack sizes may be marketed.

16. ADDITIONAL INFORMATION

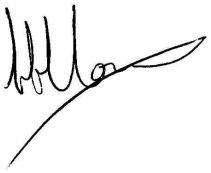
All suspected adverse reactions and any suspected lack of efficacy should be reported to 01344 746957 at Boehringer Ingelheim Animal Health UK Ltd., Ellesfield Avenue, Bracknell, Berkshire RG12 8YS.

Further information on this product and its supporting data can be found on http://www.vmd.gov.uk/ProductInformationDatabase

Keep the container in the outer carton.
For animal treatment only.
To be supplied on veterinary prescription only.

Vm 08327/4256

POM-V



Approved 29 November 2018