PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mydiavac

EAE Vaccine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Presentation: Mydiavac® is an inactivated Chlamydophila abortus vaccine for sheep containing 2x108 eb/1ml dose as a white emulsion of water in oil for intramuscular injection.

Each dose contains inactivated Chlamydophila abortus (strain B/S), adjuvanted with Marcol 52:Montanide 888 (90:10), 0.5ml/dose, preserved with thiomersal, 0.13mg/dose.

3. PHARMACEUTICAL FORM

White emulsion of water in oil

4. PACKAGE SIZE

20 ml
100 ml

5. TARGET SPECIES

Female breeding sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection

Administration: Shake well before use. Read the package leaflet before use. Administer 1ml by intramuscular injection. The recommended injection site is a point 3” to 4” in front of the shoulder in the middle of the neck.

Primary vaccination: Sheep should receive 1 dose of vaccine. Animals should be vaccinated approximately 1 month prior to mating or from 4 weeks after the ram is removed.

Booster vaccination: The primary vaccination should be repeated 771 days after the initial vaccination.

8. WITHDRAWAL PERIOD

Zero days. However, if a live Toxoplasma gondii vaccine has been administered concomitantly, the withdrawal period applicable to that vaccine should apply.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous — refer to package leaflet.

Do not administer to unhealthy animals. Do not use in cases of hypersensitivity to the adjuvant or any of the excipients. Transient pyrexia and injection site inflammatory reactions may occur. The pyrexia is not associated with any change in appetite or general demeanour. The injection site reaction, which may be palpable as a nodule of approximately 30mm in diameter, will normally resolve within 5 weeks.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Store and transport between 2°& 8°C. Do not freeze. To facilitate injection the vaccine should be removed from the refrigerator on the morning of use and kept at room temperature. Once broached the contents of the container must be used within or discarded by the end of that working day. Unused vaccine must not be returned to the refrigerator.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

POM-V

For animal treatment only

To be supplied only on veterinary prescription

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

Benchmark Animal Health Ltd
8 Smithy Wood Drive
Chapeltown
Sheffield
S35 1QN

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43684/4000

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mydiavac

EAE Vaccine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Presentation: Mydiavac® is an inactivated Chlamydophila abortus vaccine for sheep containing 2x108 eb/1ml dose as a white emulsion of water in oil for intramuscular injection.

Each dose contains inactivated Chlamydophila abortus (strain B/S), adjuvanted with Marcol 52:Montanide 888 (90:10), 0.5ml/dose, preserved with thiomersal, 0.13mg/dose.

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

20 ml or 100 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular injection

Administration: Shake well before use. Read the package leaflet before use. Administer 1ml by intramuscular injection. The recommended injection site is a point 3” to 4” in front of the shoulder in the middle of the neck.

Primary vaccination: Sheep should receive 1 dose of vaccine. Animals should be vaccinated approximately 1 month prior to mating or from 4 weeks after the ram is removed.

Booster vaccination: The primary vaccination should be repeated 771 days after the initial vaccination.

5. WITHDRAWAL PERIOD

Zero days. However, if a live Toxoplasma gondii vaccine has been administered concomitantly, the withdrawal period applicable to that vaccine should apply.

6. BATCH NUMBER

7. EXPIRY DATE

Once broached the contents of the container must be used within or discarded by the end of that working day.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

POM – V
To be supplied only on veterinary prescription
Keep out of the sight and reach of children.
VM 43684/4000

PACKAGE LEAFLET FOR:

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

Benchmark Animal Health Ltd
8 Smithy Wood Drive
Chapeltown
Sheffield
S35 1QN

Manufactured and distributed by

Benchmark Vaccines Ltd
4 Warner Drive, Springwood Industrial Estate,
Braintree, Essex CM7 2YW

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mydiavac

EAE Vaccine

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Mydiavac® is an inactivated Chlamydophila abortus vaccine for sheep containing 2x108 eb/1ml dose as a white emulsion of water in oil for intramuscular injection. Each dose contains inactivated Chlamydophila abortus (strain B/S), adjuvanted with Marcol 52:Montanide 888 (90:10), 0.5ml/dose, preserved with thiomersal, 0.13mg/dose.

4. INDICATION(S)

For the active immunisation of susceptible female breeding sheep against Chlamydophila abortus infection as an aid in the prevention of abortion caused by this organism. Studies to indicate that the protection afforded should exist for at least 771 days post initial vaccination.

5. CONTRAINDICATIONS

Do not administer to unhealthy animals. Do not use in cases of hypersensitivity to the adjuvant or any excipients.

6. ADVERSE REACTIONS

Transient pyrexia and injection site inflammatory reactions may occur (at normal and twice the recommended dose). The pyrexia is not associated with any change in

appetite or general demeanour. The injection site reaction, which may be palpable as a nodule of approximately 30mm in diameter, will normally resolve within 5 weeks. As with all vaccines occasional hypersensitivity reactions may occur, in such cases appropriate treatment should be given, e.g. an antihistamine or corticosteroid.

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

7. TARGET SPECIES

Female breeding sheep

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

Dose— 1ml to be administered intramuscularly.

The recommended injection site is a point 3” to 4” in front of the shoulder in the middle of the neck.

Primary vaccination: Sheep should receive 1 dose of vaccine. Animals should be vaccinated approximately 1 month prior to tupping or from 4 weeks after the ram is removed.

Booster vaccination: The primary vaccination should be repeated 771 days after the initial vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the container well before withdrawing the first dose and regularly during use. Syringes and needles should be sterilised before use and the injection made through an area of clean dry skin using aseptic techniques. A dosing device, i.e. vaccinating gun, may also be used.

10. WITHDRAWAL PERIOD(S)

Zero days. However, if a live Toxoplasma gondii vaccine has been administered concomitantly, the withdrawal period applicable to that vaccine should apply.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Store and transport between 2° and 8°C. Do not freeze. To facilitate injection the vaccine should be removed from the refrigerator on the morning of use and kept at room temperature. Unused vaccine must not be returned to the refrigerator. Once broached the contents of the container must be used within or discarded by the end of that working day. Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special warnings for the target species:

Some animals in any given population may not respond to vaccination as a result of immunosuppression or for other reasons.

Safety and efficacy data are available which demonstrate that this vaccine can be administered the same day but not mixed with a commercial *Toxoplasma gondii* vaccine containing live tachyzoites of the S48 strain. Simultaneous administration of Mydiavac® and such a commercial *Toxoplasma gondii* vaccine does not significantly affect the serological effect to either vaccine or cause any ill effects provided separate syringes and different sites of injection are used. Do not mix with any other vaccine or immunological product.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

Use during pregnancy:

The safety and efficacy of Mydiavac® administered to pregnant sheep has been studied in challenge experiments. These studies have demonstrated the safety of this practice. A reduction in abortion and infection was evident in pregnant ewes challenged following vaccination and in pregnant ewes vaccinated after challenge. On the basis of this evidence Mydiavac® could be used as an aid in the control of *Chlamydophila abortus* infection even on the face of an outbreak. Mydiavac® must not be administered concomitantly with live *Toxoplasma gondii* vaccines to pregnant animals.

For Animal Treatment Only

To the user:

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for

example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.>

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

POM – V To be supplied only on veterinary prescription

Vm 43684/4000

Mydiavac® is available in 20ml clear glass vials or 100ml polyethylene flexipacks. Not all pack sizes may be marketed.

Approved: 03/01/2018