SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mydiavac

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlamydophila abortus strain B/S inactivated 2 x 10^8 eb/1 ml dose

Adjuvants:
Marcol 52: Montanide 888 (90:10) 0.5 ml / dose

Excipients:
Thiomersal 0.13 mg (0.013% w/v / dose)

For a full list of excipients see Section 6.1

3. PHARMACEUTICAL FORM

A white emulsion of water in oil for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Female breeding sheep.

4.2 Indications for use (specifying the target species)

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

4.3 Contraindicatons

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

4.4 Special warnings (for each target species)

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

4.5 Special precautions for use

i) Special precautions for use in animals

No specific precautions

ii) Special precautions to be taken by the person administering the product to animals.

To the User: This veterinary medicinal 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 veterinary medicinal 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.

4.6 Adverse reactions (frequency and seriousness)

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 30 mm 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.

4.7 Use during pregnancy and lactation or lay

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 *Chlamydophyla abortus* infection, even in the face of an outbreak. Mydiavac must not be administered concomitantly with live *Toxoplasma gondii* vaccines to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on 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.

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.

4.9 Amount(s) to be administered and administration route

1 ml to be administered intramuscularly. The recommended injection site is a point 3" - 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.

Shake the container well before withdrawing the dose.
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary.

At twice the recommended dose, transient pyrexia and injection site 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 30 mm diameter, will normally resolve within 5 weeks.

4.11 Withdrawal period

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

5. IMMUNOLOGICAL PROPERTIES

Inactivated oil adjuvanted vaccine to stimulate immunity against the major outer membrane protein (MOMP) of *Chlamydophyla abortus*.

ATCVet code: Q104AB06

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal (preservative)
Marcol 52: Montanide 888 (90:10) (Adjuvant)
Phosphate buffered saline (Diluent)

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale:
14 months when presented in 100 ml flexipack.
12 months when presented in 20 ml glass packs.

Shelf-life after first opening the immediate packaging:
Once broached, the contents of the container must be used within, or discarded by the end of, that working day.

6.4 Special Precautions for Storage

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.

6.5 Nature and composition of the immediate packaging.

Size: 20 ml Type 1, clear vial
Size: 100 ml polyethylene flexipacks
Closure: Nitrile bungs with aluminium seals

Not all pack sizes may be marketed.

6.6 Special Precautions for the disposal of the Unused Product or Waste Materials.

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 AUTHORISATON HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 43684/4000

9. DATE OF FIRST AUTHORISATION

Date: 12 August 1997

10. DATE OF REVISION OF THE TEXT

Date: February 2015

APPROVED T. NASH **26/02/15**