CEVAC® CHLAMYDIA

Product information

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These pages are general information pages. No guarantee is given as to the completeness of the information contained or its compliance with national regulatory requirements. Users should consult the local site of their countries to obtain information that complies with applicable national regulations.

1. NAME OF VETERINARY MEDICINAL PRODUCT

CEVAC® CHLAMYDIA

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient Live, attenuated strain ts1B *Chlamydophila abortus* $10^{5.0}$ -$10^{6.9}$ IFU* per dose *Inclusion-body Forming Units

Cevac® Chlamydia diluents

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder plus solvent for injection.

4. CLINICAL PARTICULARS

4.1 | Target species

Susceptible female breeding sheep

4.2 | Indications for use, specifying the target species

For the active immunisation of susceptible breeding female sheep to reduce abortion caused by *Chlamydophila abortus* infection.

4.3 | Contra-indications

Do not vaccinate animals less than 4 weeks before mating. Do not vaccinate pregnant animals. Do not vaccinate animals which are being treated with antimicrobials, particularly tetracyclines.

4.4 | Special warnings for each target species

Chlamydophila abortus is only one of the causes of abortion in sheep. If abortion rates remain unchanged in flocks which have been vaccinated with Cevac® Chlamydia it is recommended that veterinary advice is sought. The epidemiology of abortion due to *Chlamydophila abortus* in ewes involves a long incubation period. Ewes that abort in any lambing season have usually been infected at the previous lambing. Field trial data indicate that vaccinating incubating ewes will reduce the incidence of abortion, but a proportion can still go on to abort. Care should be taken in handling such abortions as susceptible humans may be at risk of infection.

4.5 | Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

i Special precautions for use in animals

Not applicable.

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

Cevac® Chlamydia should not be handled by pregnant women or women of child bearing age as the vaccine may cause abortion. Cevac® Chlamydia should not be handled be persons who are immune-deficient (e.g. AIDS sufferers, persons undergoing chemotherapy or taking immune-suppressive drugs). If in any doubt, you should consult your GP. Operators should wear gloves when handling the vaccine. Care should be taken to avoid self-injection, but if this occurs, immediate medical advice should be sought and the doctor informed that self injection with a living Chlamydophila vaccine has occurred. Tetracycline therapy is the current recognised treatment for infection with *Chlamydophila abortus* in humans.

4.6 | Adverse reactions (frequency and seriousness)

A transient temperature rise may be observed after vaccination (average of 1.5°C for a maximum of 3 days).

Molecular investigations revealed the possible presence of the vaccine strain 1B in placentas collected in cases of enzootic abortion of ewes vaccinated with Cevac Chlamydophila. Although the causal relationship has not been firmly established (differential diagnosis incomplete), and the representative sampling should be specified in the domestic context, the possibility that the vaccine strain can be at the origin of abortions can not however be excluded in the present state of knowledge. This should be considered in the benefit / risk analysis conducted by the vet before prescribing the vaccine, especially in farms where the infection pressure related to *Chlamydophila abortus* is low. In very rare cases the vaccine may cause hypersensitivity reactions.

4.7 | Use during pregnancy and lactation

Do not vaccinate 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 the same day but not mixed with a commercial *Toxoplasma gondii* vaccine containing live tachyzoites of the S48 strain. 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 | Amounts to be administered and administration route

The vaccine is supplied in vials containing 10, 20, 50 or 100 doses.

Reconstitution: The vaccine is reconstituted with the solvent immediately prior to use, allowing 2 ml of diluent per dose. If using the vented transfer device push one end of the device through the centre of the vaccine vial using a firm, twisting action. Similarly, push the solvent vial onto the opposite end of the device taking care to ensure the spike penetrates the centre of the vial bung. Carefully allow diluent to flow into the vaccine vial without completely filling it. Ensure the powder plug is fully dissolved and then invert until all the vaccine solution drains into the diluent vial. Remove the empty vaccine vial and transfer spike from the diluent vial and place into an appropriate disinfectant solution. Alternatively, remove approximately 5 ml of the solvent from the vial with a syringe and needle, inject into the vaccine vial and shake well until the powder plug is fully dissolved. Remove the vaccine solution from the vial, reinject into the diluent vial and shake well. Great care should be taken not to generate an aerosol.

Administration Dose: 2 ml by intramuscular or subcutaneous injection. Ewe lambs, where it is intended to breed from them, may be vaccinated from 5 months of age. Shearlings and older ewes should be vaccinated during the 4 month period prior to mating.

Injection equipment to minimise the risk of self-injection the vaccine should be administered using automatic syringes fitted with the sterimatic guarded needle system according to the manufacturer's instructions. It is vital that a vented draw off tube is used with this equipment. Regular checks should be made to ensure the syringes are properly calibrated. Carefully attach the vial of reconstituted vaccine to the injection equipment and avoid aerosols during the priming process. It may be advisable to wear a visor while carrying out this operation.

4.10 | Overdose

No particular signs at ten times dose other than a transient temperature increase as seen with a single dose – see 4.6.

4.11 | Withdrawal periods

Meat: 7 days

5. IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QI04AE01

To stimulate active immunity against *Chlamydophila abortus*.

6. PHARMACEUTICAL PARTICULARS

6.1 | Excipients

I-glutamic acid (sodium salt)
Bovine serum albumin
Sucrose Water for injection

6.2 | Incompatibilities

Do not mix with any other veterinary medicinal product, except diluent supplied for use with the product.

6.3 | Shelf life and in-use shelf life

Shelf life as packaged for sale: 1 year Shelf life after reconstitution according to directions: 2 hours

6.4 | Special precautions for storage

Store between +2° and +8°C. Protect from light. Do not freeze.

6.5 | Nature and composition of immediate packaging

Vial of Type I Ph. Eur. Glass, closed with a rubber stopper and sealed with a colour coded aluminium cap, containing a freeze dried plug of vaccine (10, 20, 25, 50 or 100 doses) with the appropriate volume of diluent in Type II glass vials (20, 40, 100 or 200 ml). Not all pack sizes may be marketed.

6.6 | Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.