PARTICULARS TO APPEAR ON THE OUTER BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC® CHLAMYDIA

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Freeze dried vaccine containing *Chlamydophila abortus* strain 1B (at least 10^5 IFU per dose).

3. PHARMACEUTICAL FORM

Live, attenuated, freeze dried vaccine.

4. PACKAGE SIZE

1 vial of 10, 20, 25, 50 or 100 doses + 1 vial of 20, 40, 100 or 200 ml diluent.
2 vials of 10 doses

5. TARGET SPECIES

Female sheep.

6. INDICATION(S)

Active immunisation against *Chlamydophila abortus* infection in female sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat: 7 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store between +2° and +8°C. Protect from light. Do not freeze. After reconstituting, use the product in two hours. Keep the container in the outer carton.

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

Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4031

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC® CHLAMYDIA

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Chlamydophila abortus attenuated strain 1B (at least 10^5 IFU/dose 2ml).

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

10, 20, 25, 50 or 100 doses

4. ROUTE(S) OF ADMINISTRATION

Read package leaflet.

5. WITHDRAWAL PERIOD

Read package leaflet.

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

1. NAME OF THE DILUENT

CEVAC® CHLAMYDIA

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20, 40, 100 or 200 ml

3. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Keep the container in outer carton.

5. BATCH NUMBER

6. EXPIRY DATE

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PACKAGE LEAFLET

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

Marketing Authorisation Holder: Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH

Manufacturer responsible for batch release: Ceva Phylaxia, 1107 Budapest, Szállás u.5, Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Chlamydia

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

Live, attenuated 1B strain of *Chlamydophila abortus* (at least 10^5 IFU* per dose)
*Inclusion-body Forming Units
Cevac Chlamydia solvent: diluent for reconstitution.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not vaccinate animals less than 4 weeks before mating.
Do not vaccinate pregnant animals.
Do not vaccinate animals.

6. ADVERSE REACTIONS

A transient temperature rise may be observed after vaccination (average of 1.5°C for a maximum of 3 days).
In very rare cases abortions may occur where the vaccine strain can be identified.
In very rare cases the vaccine may cause hypersensitivity reactions.

7. TARGET SPECIES

Susceptible female breeding sheep.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Meat: 7 days

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNING(S)

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

Operator warnings
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.
For Animal Treatment Only- Keep out of sight and reach of children.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

POM-V

Vm 15052/4031. To be supplied only on veterinary prescription.
Vials containing 10, 20, 25, 50 or 100 doses supplied together with the solvent. Not all pack sizes may be marketed.
Chlamydiosis 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. Susceptible in-contact vaccinated ewes are protected. A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

Approved 27 September 2022