SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enzovax

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	per dose
Live, attenuated strain ts 1B *Chlamydophila abortus*	$10^{5.0}$ -$10^{6.9}$IFU*

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.
Lyophilisate: Off-white to cream-coloured pellet.
Solvent: Colourless solution.

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 female breeding sheep to reduce abortion caused by *Chlamydophila abortus* infection.
Challenge studies have demonstrated that protection against Enzootic abortion and excretion of *Chlamydophila abortus* post-challenge is undiminished for at least three years post vaccination with Enzovax.
Field studies in endemically infected flocks maintaining a policy of vaccinating incoming ewes with Enzovax indicate that enzootic abortion levels remain very low in ewes vaccinated 4 years previously.

4.3 Contraindications

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

4.4 Special warnings for each target species

Chlamydophila abortus is only one of the causes of abortion in sheep. If the abortion rate remains unchanged in flocks which have been vaccinated with Enzovax 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.
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.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

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

Enzovax should not be handled by pregnant women or women of child bearing age as the vaccine may cause abortion.
Enzovax should not be handled by persons who are immuno-deficient (e.g. AIDS sufferers, persons undergoing chemotherapy or taking immuno-suppressive drugs). If in any doubt, you should consult your GP.

To the user:
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.

To the physician:
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 up to 1.5˚C for a maximum of 3 days).
In very rare cases abortions may occur where the vaccine strain can be identified.
Hypersensitivity reactions (i.e. tachypnoea, pale mucous membranes, collapse) may occur very rarely. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrate that this vaccine can be administered the same day but not mixed with Toxovax. However, it should be given at separate sites.

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

Dose: 2 ml by intramuscular or subcutaneous injection.

Reconstitution*:*
The vaccine is reconstituted with Unisolve immediately prior to use, allowing 2 ml of solvent 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 Unisolve vial onto the opposite end of the device taking care to ensure the spike penetrates the centre of the vial bung. Carefully allow solvent to flow into the vaccine vial without completely filling it. Ensure the vaccine plug is fully dissolved and then invert until all the vaccine suspension drains into the solvent vial. Remove the empty vaccine vial and the transfer spike from the solvent vial and place them into an appropriate disinfectant solution.
Alternatively, remove approximately 5 ml of Unisolve from the vial with a syringe and needle, inject into the vaccine vial and swirl gently until the vaccine plug is fully dissolved. Remove the vaccine suspension from the vial, re-inject into the solvent vial and mix gently. Great care should be taken not to generate an aerosol. After reconstitution the vaccine should be kept cool and used as soon as possible (within 2 hours).

Administration
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.
Vaccination must take place at least 4 weeks before mating.

Injection equipment
To minimise the risk of self-injection the vaccine should be administered using a disposable automatic syringe fitted with a 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 creating aerosols during the priming process. It may be advisable to wear a visor while carrying out this operation.

Re-vaccination policy
Challenge studies have demonstrated that protection against Enzootic abortion and excretion of *Chlamydophila abortus* post-challenge is undiminished for at least three years post vaccination with Enzovax.
Re-vaccination is recommended every 3-4 years depending on farm management practices and conditions.

Field studies in endemically infected flocks maintaining a policy of vaccinating incoming ewes with Enzovax indicate that enzootic abortion levels remain very low in ewes vaccinated 4 years previously.

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

No particular symptoms at ten times dose other than a transient pyrexic response similar to that seen after a single dose but up to 2˚C.

4.11 Withdrawal period

Meat and offal: 7 days

5. IMMUNOLOGICAL PROPERTIES

ATCVet code: QI04AE01
To stimulate active immunity against *Chlamydophila abortus*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine:
Monosodium glutamate
Sucrose
Bovine serum albumin
Water for Injection.
Solvent (Unisolve):
Sucrose
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Sodium chloride
Water for Injection

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
Lyophilisate: 1 year.
Solvent: in glass vials: 5 years
in PET vials: 18 months.

Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Vaccine:
Store and transport refrigerated (2°C - 8°C).
Do not freeze. Protect from light.

Solvent:
Store below 25 °C (if stored separately). Do not freeze.

6.5 Nature and composition of immediate packaging

Carton with one vial of lyophilisate and one vial of solvent (Unisolve), and a transfer spike.

Vaccine:
Type I (Ph.Eur.) glass vial, closed with a rubber stopper and sealed with a colour coded aluminium cap, containing a freeze dried plug of vaccine (10, 20, 50 or 100 doses) for use with the appropriate volume of solvent.
Solvent (Unisolve):
Type II glass vials (Ph. Eur) containing 2, 3, 4, 7, 10, 13, 20, 25, 40, 50, 100, 200 or 400 ml closed with a halogenated butylrubber stopper and an aluminium crimp cap.
Polyethylene terephthalate (PET) vials containing 40 or 100 ml closed with a halogenated butylrubber stopper and an aluminium crimp cap.

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

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4103

9. DATE OF FIRST AUTHORISATION

26 April 1996

10. DATE OF REVISION OF THE TEXT

October 2024

Gavin Hall

Approved 16 October 2024