1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enzovax lyophilisate and solvent for suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose of reconstituted vaccine contains:

Active substance:
Chlamydia abortus, strain 1B (thermosensitive), Live, attenuated: $10^{5.0} – 10^{6.9}$ IFU*

*IFU = inclusion-body forming units.

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Monosodium glutamate
Sucrose
Bovine serum albumin
Water for injections
Solvent (Unisolve):
Sucrose
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

Lyophilisate: Off-white to cream-coloured pellet.
Solvent: Colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (ewes).

3.2 Indications for use for each target species

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

Onset of immunity: Vaccination should be conducted at least 4 weeks before mating.

Duration of immunity: Challenge studies have demonstrated that protection against enzootic abortion and excretion of *Chlamydia abortus* post-challenge is undiminished for at least three years post vaccination with the veterinary medicinal product. Field studies in endemically infected flocks

maintaining a policy of vaccinating incoming ewes with the vaccine indicate that enzootic abortion levels remain very low in ewes vaccinated 4 years previously.

3.3 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.

3.4 Special warnings

Vaccinate healthy animals only.

Chlamydia abortus is only one of the causes of abortion in sheep. If the abortion rate remains unchanged in flocks which have been vaccinated with the vaccine it is recommended that veterinary advice is sought.
The epidemiology of abortion due to *Chlamydia 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. The physician should be informed that self-injection with a living chlamydia vaccine has occurred.
Tetracycline therapy is the current recognised treatment for infection with *Chlamydia abortus* in humans.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
The veterinary medicinal product should not be handled by pregnant women or women of childbearing age as the vaccine may cause abortion.
Immunocompromised persons are advised to avoid contact with the vaccine.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Sheep (ewes):

Very common (>1 animal / 10 animals treated):	Elevated temperature[1].

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Abortion[2]; Hypersensitivity reaction (e.g. Tachypnoea, pale mucous membranes, collapse)[3].

[1]Transient and average up to 1.5 °C for a maximum of 3 days after vaccination.
[2]May occur where the vaccine strain can be identified.
[3]Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during pregnancy.

3.8 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 Toxovax. The vaccines should be given at different 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.

3.9 Administration routes and dosage

Intramuscular use or subcutaneous use.
Dose: 2 ml.

Reconstitution:
The vaccine is reconstituted with the solvent (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).

Visual appearance after reconstitution: Off-white suspension.

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.

Revaccination policy
Challenge studies have demonstrated that protection against enzootic abortion and excretion of *Chlamydia abortus* post-challenge is undiminished for at least three years post vaccination with the veterinary medicinal product.
Revaccination 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 the vaccine indicate that enzootic abortion levels remain very low in ewes vaccinated 4 years previously.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No particular clinical signs at ten times the dose other than a transient pyrexic response similar to that seen after a single dose but up to 2 °C.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 7 days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AE01.

To stimulate active immunity against *Chlamydia abortus*.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

Lyophilisate:
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.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Type I 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 vial containing 20, 40, 100 or 200 ml solvent closed with a halogenated butylrubber stopper and an aluminium crimp cap.
Polyethylene terephthalate (PET) vial containing 40 or 100 ml solvent closed with a halogenated butylrubber stopper and an aluminium crimp cap.

Pack sizes
Cardboard box with one vial of lyophilisate 10, 20, 50 or 100 doses and one vial of solvent 20, 40, 100 or 200 ml (Unisolve) respectively and a transfer spike.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/079/001

8. DATE OF FIRST AUTHORISATION

15/11/2002

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

22/07/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).