1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovilis Enzovax
Lyophilisate and solvent for suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Freeze-dried vaccine (per dose):
Active substance:
Live attenuated *Chlamydophila abortus* strain ts 1B: $10^{5.0}$ – $10^{6.9}$ IFU

IFU = inclusion-body forming units

Diluent:
Unisolve is supplied with the vaccine.

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension 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 female breeding sheep as an aid in the prevention of abortion and stillbirth caused by *Chlamydophila abortus* (previously referred to as *Chlamydia psittaci*) infection.

Onset of immunity: vaccination 4 weeks before mating has shown that susceptible ewes are protected.
Duration of immunity: 3-4 years (See also under re-vaccination policy 4.9.)

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

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 Ovilis 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.

4.5 Special precautions for use

Special precautions for use in animals

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.

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

Operators should wear gloves when handling the vaccine.
Ovilis Enzovax should not be handled by pregnant women or women of child bearing age as the vaccine may cause abortion.
Ovilis 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 seek medical advice.
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 (for a maximum of 5 days).
In very rare cases abortions may occur where the vaccine strain can be identified.

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 efficacy data are available which demonstrates that this vaccine can be administered on the same day but not mixed with Ovilis Toxovax where this product and the combined use is authorised. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except Ovilis Toxovax. 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

Reconstitution
The vaccine is reconstituted with 2 ml Unisolve per dose immediately prior to use.

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 diluent 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 diluent vial. Remove the empty vaccine vial and the transfer spike from the diluent 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 solution from the vial, re-inject into the diluent vial and mix gently. Great care should be taken not to generate an aerosol.

Administration
One dose of 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.
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 Ovilis Enzovax.
Field studies in endemically infected flocks maintaining a policy of vaccinating incoming ewes with Ovilis 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 signs at ten times dose other than a transient temperature increase as seen with a single dose.

4.11 Withdrawal period(s)

Meat: 7 days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live bacterial vaccines for sheep
ATC vet code: QI04AE01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monosodium glutamate
Sucrose
Bovine serum albumin
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Sodium chloride
Water for infections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale
Lyophilisate: Up to 24 months at -20°C (by manufacturer) followed by 1 year at 2-8°C
Solvent: glass vials 5 years
PET vials 24 months

Shelf life after dilution or reconstitution according to directions
2 hours

6.4. Special precautions for storage

Lyophilisate:
Store and transport refrigerated (2°C - 8°C). Do not freeze. Protect from light.
After reconstitution the vaccine should be used as soon as possible (within 2 hours).

Solvent
The solvent can be kept at 15-25°C if stored separately from the lyophilisate.

6.5 Nature and composition of immediate packaging

Card board box containing 1 vial of vaccine / 1 vial of Unisolve.

Lyophilisate:
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, 50 or 100 doses).

Solvent:
Vial of Type II glass or PET containing the appropriate volume (20, 40, 100 or 200 ml).
Not all presentations 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

The national representative of:
Intervet International BV
Wim de Körverstraat 35
NL – 5831 AN Boxmeer

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

RMS: 15-03-2000

10 DATE OF REVISION OF THE TEXT

March 2011