1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Toxovax concentrate and solvent for suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose of reconstituted vaccine contains:

Active substance:
Toxoplasma gondii tachyzoites S48: $\geq 10^5$

Excipients:

Qualitative composition of excipients and other constituents
Concentrate:
DMSO
Bovine serum
Tryptose
Sucrose
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Sodium chloride
Water for injections
Solvent (Unisolve):
Sucrose
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Sodium chloride
Water for injections

Concentrate: Cloudy suspension.
Solvent (Unisolve): 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 breeding female sheep to reduce the effects of infection by *Toxoplasma gondii*, namely early embryonic death, barrenness and abortion.

Duration of immunity: Vaccination with the veterinary medicinal product is known to protect for at least two lambing seasons.

3.3 Contraindications

Do not vaccinate animals less than 3 weeks before mating.
Do not use during pregnancy.

3.4 Special warnings

Toxoplasma is only one of the causes of abortion in sheep.
Where abortion occurs in sheep which have been vaccinated with the veterinary medicinal product then it is recommended that veterinary advice is sought immediately to clarify the likely cause.
Care should be taken when 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.

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection and to avoid vaccine getting into the mouth or the eyes.
In case of accidental self-injection, ingestion or spillage onto skin, 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 tachyzoite toxoplasma vaccine has occurred.
Pyrimethamine therapy is the current recognised treatment for toxoplasmosis 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 interfere with normal foetal development.
Living tachyzoites can be pathogenic for humans. Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.
Immunocompromised persons are advised to avoid contact with the vaccine (e.g., AIDS sufferers; persons undergoing chemotherapy or taking immunosuppressive drugs).

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

3.6 Adverse events

Sheep (ewes):

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

[1] Transient, up to 41°C is normally observed. The temperature returns to normal within 7-8 days after vaccination.

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 Enzovax. 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

The vaccine is supplied as a liquid concentrate containing 20 or 50 doses.
Immediately before use this is added to the 40 or 100 ml (respectively) solvent (Unisolve), giving a dose volume of 2 ml.

Injection equipment:
To minimise the risk of self-injection the vaccine should be administered using disposable automatic syringes fitted with a guarded needle system according to the manufacturer's instructions.
An administration kit including a vented transfer device for vaccine reconstitution and disposable automatic syringe with a guarded needle system is available from the company.
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.

Reconstitution:
Protective gloves (impervious rubber or plastic such as disposable medical gloves or surgical gloves (EU standards)) and goggles or a face visor should be worn when reconstituting the vaccine.
If using the vented transfer device push one end of the device through the centre of the solvent vial using a firm, twisting action. Similarly, push the vaccine vial onto the opposite end of the device taking care to ensure the spike penetrates the centre of the vial bung. The vaccine concentrate will drain into the solvent vial. Remove the empty vaccine vial and transfer spike from the solvent vial and place into an appropriate disinfectant solution.
Alternatively, withdraw the entire contents of the vaccine concentrate vial using a sterile disposable 10 ml syringe and either a 16 G or 18 G sterile needle. Carefully expel any air from the syringe and inject the contents into the solvent vial.
With the solvent vial upright withdraw 5-10 ml of air prior to removing the needle. This maintains the vial under negative pressure and avoids spillage when the needle is removed.
After reconstitution the vaccine should be kept cool and away from light and used as soon as possible (within 2 hours).
Ideally only reconstitute one vaccine vial at a time.

Administration
Intramuscular use.
Dose: 2 ml.

Basic vaccination:
Animals should be given a single dose at least 3 weeks prior to mating. 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.

Revaccination:
After 2 years, a single dose at least 3 weeks prior to mating.

Visual appearance after reconstitution: Cloudy suspension.

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

At 20 times the dose a transient temperature increase as seen with a single dose but up to 41.5 °C - 42 °C was observed.

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: 42 days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AN01.

To stimulate active immunity against *Toxoplasma gondii*.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
Concentrate: 10 days.
Solvent (Unisolve): in glass vials: 60 months; in PET vials: 18 months.

Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

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

Solvent (Unisolve):
Store below 25 °C (if stored separately).

Do not freeze.

5.4 Nature and composition of immediate packaging

Vaccine:
Glass vial, hydrolytical class Type I, closed with a halogenobutyl rubber stopper and sealed with a colour coded aluminium cap, containing 2 ml (20 doses) or 5 ml (50 doses) of vaccine concentrate.

Solvent (Unisolve):
Glass vial, hydrolytical class Type II, or PET (polyethylene terephthalate) vials, closed with a halogenobutyl rubber stopper and sealed with an aluminium crimp cap containing 40 ml (for 20 doses) or 100 ml (for 50 doses) solvent.

Vaccine, solvent (Unisolve) and a transfer spike packed together or separately
Pack sizes:
Cardboard box with 1 x vial of 20 doses of vaccine and 1 x vial of 40 ml of solvent and a transfer spike.
Cardboard box with 1 x vial of 50 doses of vaccine and 1 x vial of 100 ml of solvent and a transfer spike.
Cardboard box with 1 x vial of 20 doses of vaccine and a cardboard box with 1 x vial of 40 ml of solvent (add transfer spike if appropriate to either cardboard box).
Cardboard box with 1 x vial of 50 doses of vaccine and a cardboard box with 1 x vial of 100 ml of solvent (add transfer spike if appropriate to either cardboard box).

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 in accordance with national requirements.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/080/001

8. DATE OF FIRST AUTHORISATION

18/08/2003

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

15/07/2025

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).