Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Toxovax

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose of diluted vaccine contains:

Active substance:
≥ 10^5 *Toxoplasma gondii* tachyzoites S48

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate and diluent for suspension for injection.
Concentrate: cloudy suspension.
Diluent (Unisolve) : colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep (ewes).

4.2 Indications for use, specifying the 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.
Vaccination with Toxovax is known to protect for at least two lambing seasons.

4.3 Contraindications

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

4.4 Special warnings for each target species

Toxoplasma is only one of the causes of abortion in sheep. Where abortion occurs in sheep which have been vaccinated with Toxovax then it is recommended that veterinary advice is sought immediately to clarify the likely cause. 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. Immuno-competence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.
Only healthy animals should be vaccinated.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special Precautions to be taken by the person administering the product to animals

Toxovax should not be handled by pregnant women, or women of child bearing age as the vaccine may interfere with normal foetal development.
Toxovax should not be handled by persons who are immuno-deficient (eg. AIDS sufferers; persons undergoing chemo-therapy or taking immuno-suppressive drugs).
Operators should wear gloves when handling the vaccine.
Living tachyzoites can cause disease in man.
Care should be taken to avoid self-injection and to avoid vaccine getting into the mouth or the eyes. In the case of self-injection, immediate medical advice should be sought and the doctor 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.

4.6 Adverse reactions (frequency and seriousness)

A transient temperature rise is normally observed (up to 41°C returning to normal within 7-8 days of vaccination).

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Enzovax.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except Enzovax. 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

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) diluent, 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 devise 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 reconstitutedvaccine 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.

Dilution:
Protective gloves (impervious rubber or plastic such as disposable medical gloves or surgical gloves (EU standrads) and goggles or a face visor should be worn when diluting the vaccine.

If using the vented transfer device push one end of the device through the centre of the diluent 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 diluent vial. Remove the empty vaccine vial and transfer spike from the diluent 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 16g or 18g sterile needle. Carefully expel any air from the syringe and inject the contents into the diluent vial. With the diluent 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 dilution the vaccine should be kept cool and away from light and used as soon as possible (within 2 hours). Ideally only dilute one vaccine vial at a time.

Administration
Dose: 2 ml by intramuscular injection,

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.

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

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

No particular signs at 20 times dose other than a transient temperature increase as seen with a single dose but up to 41.5 - 42°C.

4.11 Withdrawal period(s)

Meat and offal: 42 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live parasitic vaccines, toxoplasma.
ATC vet code: QI04AN01

To stimulate active immunity against *Toxoplasma gondii*.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine:
DMSO
Bovine Serum
Tryptose
Sucrose
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Sodium chloride
Water for injection

Diluent (Unisolve) :
Sucrose
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Sodium chloride
Water for injection

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
Concentrate: 10 days.
Diluent (Unisolve) : in glass vials: 60 months; in PET vials: 18 months.
Shelf life after dilution according to directions: 2 hours

6.4 Special precautions for storage

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

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

6.5 Nature and composition of immediate packaging

Vaccine, solvent (Unisolve) and a transfer spike packed together or separately
Pack sizes:

Carton box with 1 vial of 20 doses of vaccine and a vial of 40 ml of diluent, and a transfer spike.
Carton box with 1 vial of 50 doses of vaccine and a vial of 100ml of diluent, and a transfer spike.
Carton box with 1 vial of 20 doses of vaccine and a carton box with 40ml of diluent (add transfer spike if appropriate to either carton).
Carton box with 1 vial of 50 doses of vaccine and a carton box with 100ml of diluent (add transfer spike if appropriate to either carton).

Vaccine:
Type I Ph.Eur. glass vials, 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.

Diluent (Unisolve) :
Hydrolytic Type II Ph. Eur. glass, or PET (polyethylene terephthalate) vials with halogenated butyl rubber stopper and an aluminium crimp cap containing 40 ml (for 20 doses) or 100 ml (for 50 doses) diluent.

Not all pack sizes may be marketed.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/080/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th August 2008

10 DATE OF REVISION OF THE TEXT

December 2021