

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON**

<Sheep pictogram>

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Toxovax  
Concentrate and diluent for suspension for injection

Or  
Toxovax  
Concentrate for suspension for injection

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each 2 ml dose of diluted vaccine contains:  $\geq 10^5$  *Toxoplasma gondii* tachyzoites S48.

**3. PHARMACEUTICAL FORM**

Concentrate and diluent for suspension for injection.

**4. PACKAGE SIZE**

1 x vial Toxovax (concentrate)  
1 x vial Unisolve (diluent)  
1 x transfer spike

Or  
1 x vial Toxovax (concentrate)

20 doses  
50 doses

**5. TARGET SPECIES**

Sheep (ewes).

**6. INDICATION(S)**

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.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: 2 ml. Route: Intramuscular injection.  
Read the package leaflet before use.

Transfer spike will be supplied separately (detail to be included for Toxovax only pack).

## 8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 42 days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Warnings: Read the package leaflet before use.

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.

## 10. EXPIRY DATE

Expiry: {dd-mm-yyyy}

Once diluted, use within 2 hours.

## 11. SPECIAL STORAGE CONDITIONS

Keep the containers in the outer carton.

Concentrate (Toxovax):

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

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.  
To be supplied only on veterinary prescription.

UK: POM-V

IE: POM

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**UK only:**

Vm 01708/4331

POM-V

**IE only:**

VPA 10996/080/001

POM

**MA Holder in the UK:**

MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
MK7 7AJ, UK

**MA Holder in Ireland and distributor in Northern Ireland:**

Intervet Ireland Ltd.  
Magna Drive, Magna Business Park  
Citywest Road  
Dublin 24, Ireland

**16. MARKETING AUTHORISATION NUMBER(S)**

UK: Vm 01708/4331

IE: VPA 10996/080/001

**17. MANUFACTURER'S BATCH NUMBER**

Batch: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**LABEL**

Insert Sheep pictogram

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Toxovax  
Concentrate

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Per 2 ml dose of diluted vaccine:  $\geq 10^5$  *Toxoplasma gondii* tachyzoites S48.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

20 doses  
50 doses

**4. ROUTE(S) OF ADMINISTRATION**

Route: IM injection.  
Dilute with Unisolve before use.

**5. WITHDRAWAL PERIOD**

**Withdrawal period:** Meat and offal: 42 days.

**6. BATCH NUMBER**

Batch: {number}

**7. EXPIRY DATE**

Expiry date: {dd-mm-yyyy}

Once diluted, use within 2 hours.

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.  
Read package leaflet before use.

UK: **POM-V** Vm 01708/4331.  
MSD Animal Health UK Ltd.

IE: **POM** VPA 10996/080/001.  
Intervet Ireland Ltd.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON) OF THE SOLVENT**

**CARTON (Solvent packed separately only)**

**1. NAME OF THE SOLVENT**

Unisolve

**2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

40 ml

100 ml

**3. ROUTE(S) OF ADMINISTRATION**

Read package leaflet before use.

**4. STORAGE CONDITIONS**

Store below 25 °C. Do not freeze.

Keep the container in the outer carton.

**5. BATCH NUMBER**

Batch: {number}

**6. EXPIRY DATE**

EXP end of: {month/year}

**7. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

Solvent / Diluent for use with veterinary vaccines

**IE Only:**

VPA 10996/080/001

**POM**

**UK only:**

Vm 01708/4331

**POM-V**

**PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT**

**1. NAME OF THE SOLVENT**

Unisolve

**2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

40 ml  
100 ml

**3. ROUTE(S) OF ADMINISTRATION**

Read package leaflet before use.

**4. STORAGE CONDITIONS**

Store below 25 °C. Do not freeze.  
Keep the container in the outer carton.

**5. BATCH NUMBER**

Batch: {number}

**6. EXPIRY DATE**

EXP end of: {month/year}

**7. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

Solvent / Diluent for use with veterinary vaccines

**UK only**  
POM-V Vm 01708/4331

**IE only**  
POM VPA 10996/080/001

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:**  
Toxovax

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER  
AND OF THE MANUFACTURING AUTHORISATION HOLDER  
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holders:

**MA Holder in the UK:**

MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ, UK

**MA Holder in Ireland:**

Intervet Ireland Ltd.  
Magna Drive  
Magna Business Park  
Citywest Road  
Dublin 24  
Ireland

Manufacturer responsible for batch release:

Intervet International BV  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Toxovax  
Concentrate and diluent for suspension for injection

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER  
INGREDIENT(S)**

Each 2 ml dose of diluted vaccine contains:  
 $\geq 10^5$  *Toxoplasma gondii* tachyzoites S48.

Concentrate: Cloudy suspension.  
Diluent (Unisolve): Colourless  
solution.

#### **4. INDICATION(S)**

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.

#### **5. CONTRAINDICATIONS**

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

#### **6. ADVERSE REACTIONS**

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

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

#### **7. TARGET SPECIES**

Sheep (ewes).

#### **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Dose: 2 ml.

Route of administration: Intramuscular injection.

##### *Administration*

##### **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.

#### **9. ADVICE ON CORRECT ADMINISTRATION**

The vaccine is supplied as a liquid concentrate containing 20 or 50 doses.

Immediately before use, this is added to 40 ml or 100 ml (respectively) diluent (Unisolve).

*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.

*Dilution:*

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 diluting the vaccine.

If using the vented transfer device push one end of the device through the centre of the Unisolve 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 16 G or 18 G 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.

## **10. WITHDRAWAL PERIOD**

Meat and offal: 42 days

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

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.

Keep the containers in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton.

Shelf life after dilution according to directions: 2 hours.

## **12. SPECIAL WARNING(S)**

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.

Immunocompetence 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.

Special precautions for use in animals:

None.

Special precautions to be taken by the person administering the veterinary medicinal 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 (e.g. AIDS sufferers; persons undergoing chemotherapy 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.

Pregnancy:

Do not use during pregnancy.

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.

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.

Overdose (symptoms, emergency procedures, antidotes):

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.

Incompatibilities:

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

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

November 2021

**15. OTHER INFORMATION**

ATC vet code: QI04AN01.

Pharmacotherapeutic group: Live parasitic vaccines, toxoplasma.

To stimulate active immunity against *Toxoplasma gondii*.

For animal treatment only.

To be supplied only on veterinary prescription.

*Pack sizes:* 20 doses and 50 doses.

Not all pack sizes may be marketed.

**UK only:**

Vm 01708/4331

POM-V

To be supplied only on  
veterinary prescription.

**IE only:**

VPA 10996/080/001

POM

Prescription Only  
Medicine.

**Distributor in Northern Ireland:**

Intervet Ireland Ltd., Magna Drive, Magna Business Park, Citywest Road,  
Dublin 24, Ireland

Approved: 09/12/21

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending to the right from the end of the name.