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: ≥ 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 06376/4102
POM-V

IE only:
VPA 10996/080/001
POM

MA Holder in the UK:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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)

Vm 06376/4102

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: ≥ 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 06376/4102
Intervet International B.V.

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 06376/4102
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 06376/4102

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:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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:
≥ 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 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 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 beadministered on the same day but not mixed with Enzovax.
No information is available on the safety and efficacy of this vaccine when used withany other veterinary medicinal product except Enzovax. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to bemade on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):
No particular signs at 20 times dose other than a transient temperature increase asseen 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 foruse with the product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT ORWASTE MATERIALS, IF ANY

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

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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 06376/4102

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

Gavin Hall

Approved 16 October 2024