PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enzovax

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 2 ml dose of reconstituted vaccine contains:

$10^{5.0}$-$10^{6.9}$ IFU live, attenuated *Chlamydophila abortus* strain ts 1B.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

10 doses
20 doses
50 doses

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the active immunisation of susceptible female breeding sheep to reduce abortion caused by *Chlamydophila abortus* infection.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.
Dose: 2 ml, Route: Intramuscular or subcutaneous injection.
Reconstitute with Unisolve before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 7 days

9. SPECIAL WARNING(S), IF NECESSARY

Operators should wear gloves when handling the vaccine.
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.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Lyophilisate (Enzovax): 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.

Once reconstituted, use within 2 hours.
Keep the container in the outer carton.

12. SPECIFIC 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

[Distribution category]

For animal treatment only.

UK only
Vm 01708/4523
POM-V

To be supplied only on veterinary prescription

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

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

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4523

17. MANUFACTURER'S BATCH NUMBER

Batch number:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enzovax
Lyophilisate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 2 ml of reconstituted vaccine: $10^{5.0}$ - $10^{6.9}$ IFU *Chlamydophila abortus* strain ts IB.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER PF DOSES

10 Doses
20 Doses
50 Doses

4. ROUTE(S) OF ADMINISTRATION

Route: IM or SC injection.

Reconstitute with Unisolve before use.
Once reconstituted, use within 2 hours.

5. WITHDRAWAL PERIOD

Meat and offal: 7 days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

Expiry end of:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

UK: **POM -V**

Vm 01708/4523

MSD Animal Health UK Ltd.

PACKAGE LEAFLET FOR:

Enzovax

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

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

Manufacturer for batch release
Intervet International B.V.
Wim de Korverstraat 35
5831 AN Boxmeer
The Netherlands.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enzovax
Lyophilisate and solvent for suspension for injection.

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

Each 2 ml dose of reconstituted vaccine contains:
$10^{5.0}$ -$10^{6.9}$ IFU* live, attenuated *Chlamydophila abortus* strain ts 1B.
*Inclusion-body Forming Units

Lyophilisate: off-white to cream-coloured pellet.Solvent: colourless solution.

4. INDICATION(S)

For the active immunisation of susceptible female breeding sheep to reduce abortion caused by *Chlamydophila abortus* infection.

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 Enzovax.

Field studies in endemically infected flocks maintaining a policy of vaccinating incoming ewes with Enzovax indicate that enzootic abortion levels remain very low in ewes vaccinated 4 years previously

5. 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.

6. ADVERSE REACTIONS

A transient temperature rise may be observed after vaccination (average of up to 1.5˚C for a maximum of 3 days).

No particular symptoms at ten times dose other than a transient pyrexic response similar to that seen after a single dose but up to 2˚C.

In very rare cases abortions may occur where the vaccine strain can be identified.

Hypersensitivity reactions (i.e. tachypnoea, pale mucous membranes, collapse) may occur very rarely. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

7. TARGET SPECIES

Susceptible female breeding sheep.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF AMINISTRATION

Dose: 2 ml by intramuscular or subcutaneous injection.

Reconstitution:
The vaccine is reconstituted with Unisolve immediately prior to use, allowing 2 ml of solvent per dose.

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 solvent 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 solvent vial. Remove the empty vaccine vial and the transfer spike from the solvent 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 suspension from the vial, re-inject into the solvent vial and mix gently. Great care should be taken not to generate an aerosol. After reconstitution the vaccine should be kept cool and used as soon as possible (within 2 hours).

Administration

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.

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 Enzovax.

Re-vaccination is recommended every 3-4 years depending on farm management practices and conditions.

Field studies in endemically infected flocks maintaining a policy of vaccinating incoming ewes with Enzovax indicate that enzootic abortion levels remain very low in ewes vaccinated 4 years previously.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 7 days

11. SPECIAL STORAGE PRECAUTIONS

Lyophyilisate

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.
Shelf life after dilution or reconstitution according to directions 2 hours

Keep out of the reach and sight of children. Keep the container in the outer carton.
Do not use after the expiry date stated on the carton.

12. SPECIAL WARNING(S)

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 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.
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.

Operator warnings
Enzovax should not be handled by pregnant women or women of child bearing age as the vaccine may cause abortion.
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 consult your GP.

Operators should wear gloves when handling the vaccine.

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.

Interactions
Safety/and or efficacy data are available which demonstrate that this vaccine can be administered the same day but not mixed with Toxovax. However, it should be given at separate 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.
Do not mix with any other veterinary medicinal product except the solvent (Unisolve) supplied.

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 approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2022

15. OTHER INFORMATION

For animal treatment only.

ATC Vet code:QI04AE01

To stimulate active immunity against *Chlamydophila abortus.*

Pack sizes

Carton with one vial of vaccine and one vial of solvent (Unisolve), and a transfer spike.
Vaccine: glass vial containing a freeze dried plug of vaccine (10, 20, 50 or 100 doses) for use with the appropriate volume of solvent.

Solvent (Unisolve): glass vial containing 20, 40, 100 or 200 ml of solvent, or polyethylene terephthalate (PET) vials containing 40 or 100 ml of solvent.

Not all pack sizes may be marketed.

LEGAL CATEGORY: POM-V

To be supplied only on veterinary prescription.

MA number: Vm 01708/4523

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

Approved 17 February 2022