SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovilis Enzovax lyophilisate and solvent for suspension for injection for sheep.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) of reconstituted vaccine contains:

Active substances:
Chlamydia abortus, strain 1B (thermosensitive), live, attenuated $10^{5.0}$ – $10^{6.9}$ IFU

IFU = inclusion-body forming units

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Monosodium glutamate
Sucrose
Bovine serum albumin
Water for injections
Solvent:
Sucrose
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

Concentrate: pale pink and yellow pellet.
Solvent: colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the active immunisation of susceptible female breeding sheep as an aid in the prevention of abortion and stillbirth caused by *Chlamydia abortus* (previously referred to as *Chlamydia psittaci*) infection.

Onset of immunity: vaccination 4 weeks before mating has shown that susceptible ewes are protected.
Duration of immunity: 3-4 years (See also under re-vaccination policy 3.9).

3.3 Contraindications

Do not use in pregnant animals.

Do not use in animals less than 4 weeks before mating.
Do not use in animals which are being treated with antibiotics, particularly tetracyclines.

3.4 Special warnings

Vaccinate healthy animals only.

Chlamydia abortus is only one of the causes of abortion in sheep. If the abortion rate remains unchanged in flocks which have been vaccinated with this veterinary medicinal product, it is recommended that veterinary advice is sought.

The epidemiology of abortion due to *Chlamydia 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Operators should wear gloves when handling the vaccine.
The veterinary medicinal product should not be handled by pregnant women or women of child bearing age as the vaccine may cause abortion.
The veterinary medicinal product should not be handled by persons who are immuno-deficient (e.g. AIDS sufferers, persons undergoing chemotherapy or taking immune-suppressive drugs). If in any doubt, you should seek medical advice.
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 chlamydia vaccine has occurred. Tetracycline therapy is the current recognised treatment for infection with *Chlamydia abortus* in humans.

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

3.6 Adverse events

Sheep:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Abortion[2]

[1] For a maximum of 5 days after vaccination.
[2] In which the vaccine strain can be detected.

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.

{< > to be adjusted nationally}

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 demonstrates that this vaccine can be administered on the same day but not mixed with Ovilis Toxovax where this product and the combined use is authorised. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except Ovilis Toxovax. 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

Reconstitution
The vaccine is reconstituted with 2 ml solvent per dose immediately prior to use.
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 solvent vial onto the opposite end of the device taking care to ensure the spike penetrates the centre of the vial bung. Carefully allow diluent 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 diluent vial. Remove the empty vaccine vial and the transfer spike from the diluent vial and place them into an appropriate disinfectant solution.
Alternatively, remove approximately 5 ml of solvent 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 solution from the vial, re-inject into the diluent vial and mix gently. Great care should be taken not to generate an aerosol.

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.
An administration kit including a vented transfer device for vaccine reconstitution and disposable automatic syringe with the Sterimatic® guarded needle system is available from the company.

Visual appearance after reconstitution: off-white suspension.

Primary vaccination
One dose of 2 ml by intramuscular or subcutaneous injection.
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 *Chlamydia abortus* post-challenge is undiminished for at least three years post vaccination with this veterinary medicinal product.

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

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

No particular signs at ten times dose other than a transient temperature increase as seen with a single dose.

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
{to be adjusted nationally}

3.12 Withdrawal periods

Meat: 7 days

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AE01

Live Chlamydia vaccine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Lyophilisate: Shelf life of the veterinary medicinal product as packaged for sale: 1 year.
Solvent: Shelf life of the veterinary medicinal product as packaged for sale: glass vials 5 years; PET vials 18 months.

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

5.3 Special precautions for storage

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

Solvent:
Store below 25 °C. Do not freeze.

5.4 Nature and composition of immediate packaging

Cardboard box containing 1 vial of vaccine / 1 vial of solvent.

Lyophilisate:

Vial of Type I Ph.Eur. glass, closed with a rubber stopper and sealed with a colour coded aluminium cap, containing a freeze dried plug of vaccine (10, 20, 50 or 100 doses).

Solvent:
Vial of Type II glass or PET containing the appropriate volume (20, 40, 100 or 200 ml).

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>.
{< > to be adjusted nationally}

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}
{to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
{to be completed nationally}

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

{ MM/YYYY}
{to be completed nationally}

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).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovilis Enzovax lyophilisate and solvent for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) of reconstituted vaccine contains:

Chlamydia abortus, strain 1B (thermosensitive), live, attenuated $10^{5.0}$ – $10^{6.9}$ IFU per dose
IFU = inclusion-body forming units

3. PACKAGE SIZE

1 vial lyophilisate (10, 20, 50 or 100 doses)
1 vial solvent (20, 40, 100 or 200 ml)

4. TARGET SPECIES

Sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods: meat 7 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. Protect from light. Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name or company name or logo name of the marketing authorisation holder}
{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

{national number}
{to be completed nationally}

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VACCINE VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovilis Enzovax lyophilisate and solvent for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Chlamydia abortus, strain 1B (thermosensitive), live, attenuated $10^{5.0}$ – $10^{6.9}$ IFU per dose (2 ml)
IFU = inclusion-body forming units

1 vial lyophilisate (10, 20, 50 or 100 doses)

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: meat 7 days.

6. EXPIRY DATE

Exp.{mm/yyyy}

Once reconstituted use within 2 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. Protect from light. Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name or company name or logo name of the marketing authorisation holder}
{to be completed nationally}

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VACCINE VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovilis Enzovax

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Chlamydia abortus, strain 1B (thermosensitive), live, attenuated $10^{5.0}$ – $10^{6.9}$ IFU per dose (2 ml)
IFU = inclusion-body forming units

10 doses
20 doses
50 doses
100 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

PARTICULARS TO APPEAR ON IMMEDIATE VIAL (LABEL) OF THE SOLVENT

SOLVENT VIAL

1. NAME OF THE SOLVENT

Unisolve
Solvent for Ovilis Enzovax

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

20 ml
40 ml,
100 ml
200 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store below 25°C. Do not freeze.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ovilis Enzovax lyophilisate and solvent for suspension for injection for sheep.

2. Composition

Each dose (2 ml) of reconstituted vaccine contains:

Active substances:
Chlamydia abortus, strain 1B (thermosensitive), live, attenuated $10^{5.0} – 10^{6.9}$ IFU

IFU = inclusion-body forming units

Concentrate: pale pink and yellow pellet.
Solvent: colourless solution.

3. Target species

Sheep.

4. Indications for use

For the active immunisation of susceptible female breeding sheep as an aid in the prevention of abortion and stillbirth caused by *Chlamydia abortus* (previously referred to as *Chlamydia psittaci*) infection.

Onset of immunity: vaccination 4 weeks before mating has shown that susceptible ewes are protected.
Duration of immunity: 3-4 years (See also under re-vaccination policy).

5. Contraindications

Do not use in pregnant animals.
Do not use in animals less than 4 weeks before mating.
Do not use in animals which are being treated with antibiotics, particularly tetracyclines.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Chlamydia abortus is only one of the causes of abortion in sheep. If the abortion rate remains unchanged in flocks which have been vaccinated with this veterinary medicinal product it is recommended that veterinary advice is sought.

The epidemiology of abortion due to *Chlamydia 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.

Special precautions for safe use in the target species:
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Operators should wear gloves when handling the vaccine.
The veterinary medicinal product should not be handled by pregnant women or women of child bearing age as the vaccine may cause abortion.
The veterinary medicinal product should not be handled by persons who are immuno-deficient (e.g. AIDS sufferers, persons undergoing chemotherapy or taking immune-suppressive drugs). If in any doubt, you should seek medical advice.
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 chlamydia vaccine has occurred. Tetracycline therapy is the current recognised treatment for infection with *Chlamydia abortus* 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 demonstrates that this vaccine can be administered on the same day but not mixed with Ovilis Toxovax where this product and the combined use is authorised. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except Ovilis Toxovax. 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:
No particular signs at ten times dose other than a transient temperature increase as seen with a single dose.

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

7. Adverse events

Sheep:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Abortion[2]

[1] For a maximum of 5 days after vaccination.
[2] In which the vaccine strain can be detected.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

8. Dosage for each species, routes and method of administration

Primary vaccination
One dose of 2 ml by intramuscular or subcutaneous injection.
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 *Chlamydia abortus* post-challenge is undiminished for at least three years post vaccination with this veterinary medicinal product.
Field studies in endemically infected flocks maintaining a policy of vaccinating incoming ewes with this veterinary medicinal product indicate that enzootic abortion levels remain very low in ewes vaccinated 4 years previously.

9. Advice on correct administration

Reconstitution
The vaccine is reconstituted with 2 ml solvent per dose immediately prior to use.
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 solvent vial onto the opposite end of the device taking care to ensure the spike penetrates the centre of the vial bung. Carefully allow diluent 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 diluent vial. Remove the empty vaccine vial and the transfer spike from the diluent vial and place them into an appropriate disinfectant solution.
Alternatively, remove approximately 5 ml of solvent 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 solution from the vial, re-inject into the diluent vial and mix gently. Great care should be taken not to generate an aerosol.

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.
An administration kit including a vented transfer device for vaccine reconstitution and disposable automatic syringe with the Sterimatic® guarded needle system is available from the company.

Visual appearance after reconstitution: off-white suspension.

10. Withdrawal periods

Meat: 7 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Lyophilisate:

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

Solvent:
Store below 25 °C. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or <household waste>.
{< > to be adjusted nationally}

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{to be completed nationally}

Pack sizes: Cardboard box containing 1 vial of vaccine / 1 vial of solvent.
1 vial lyophilisate (10, 20, 50 or 100 doses).
1 vial solvent (20, 40, 100 or 200 ml).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}
{to be completed nationally}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:
{< > to be adjusted nationally}

Manufacturer responsible for batch release: {to be adjusted nationally if included in the above}
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

<Local representatives <and contact details to report suspected adverse events>:>
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
{< > to be adjusted nationally}

17. Other information

{to be completed nationally}