Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 1 of 11
Pack Sizes: 100mL, 250mL, 500mL	Date (Version Control): 05/04/2013
Description: IMMEDIATE CONTAINER LABEL	APVMA: 61563/49252
Panel labels, text above the header and below the footer are r	ot included in this label text.

FOR ANIMAL TREATMENT ONLY

Coopers Ovilis CampyVax[™] –Campylobacter Vaccine for Sheep.

ACTIVE CONSTITUENTS:

Inactivated whole cell preparations of Campylobacter jejuni 1 x 10⁸ orgs/mL and

Campylobacter fetus fetus 1×10^8 orgs/mL.

Preservative: 0.1mg/mL Thiomersal.

For use as an aid in control of reproductive losses (including abortions) due to *Campylobacter* infections in sheep.

READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT.

Shake well to mix before use and to keep mixed during use

Dose:

2 mL by subcutaneous injection into the neck.

Vaccination schedule: Unvaccinated breeding ewes should receive a sensitiser vaccination prior to joining and a booster dose a minimum of 3 weeks later. Thereafter, all breeding ewes should receive an annual booster before joining.

It is essential that ewe lambs, maiden ewes, and newly purchased breeding ewes receive two vaccinations before introduction to the breeding flock.

Whole flock vaccination is recommended.

FIRST AID:

If poisoning occurs, contact a doctor or Poisons Information Centre. Australia Phone 131 126.

USER SAFETY INFORMATION: Extreme caution should be used when injecting oil emulsion vaccines to avoid injecting yourself. Accidental self-inoculation may cause inflammatory reactions or allergic response which requires correct medical management. Medical advice should be sought as soon as possible in the event of self inoculation. Do not splash in eyes. Rinse off skin and eyes with water. Keep out of reach of children.

WITHHOLDING PERIOD: Meat: NIL Milk: NIL Wool: NIL

TRADE ADVICE: Export Slaughter Interval (ESI): ESI not required.



Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 2 of 11
Pack Sizes: 100mL, 250mL, 500mL	Date (Version Control): 05/04/2013
Description: IMMEDIATE CONTAINER LABEL	APVMA: 61563/49252
Panel labels, text above the header and below the footer are not included in this label text.	

COOPERS ANIMAL HEALTH (A division of Intervet Australia Pty Ltd) 91-105 Harpin St, Bendigo East VIC 3550 STORE at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. KEEP OUT OF REACH OF CHILDREN. APVMA Approval No. 61563/49252 Contents: 100mL (50 DOSES), 250mL (125 DOSES), 500 mL (250 DOSES)

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Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 3 of 11
Pack Sizes: 100mL, 250mL, 500mL	Date (Version Control): 05/04/2013
Description: Carton Text – Front Panel	APVMA:61563/49252
Panel labels, text above the header and below the footer are not included in this label text.	

*Coopers Ovilis CampyVax*TM – Campylobacter *Vaccine for Sheep*.

ACTIVE CONSTITUENTS:

Inactivated whole cell preparations of Campylobacter jejuni 1 x 10⁸ orgs/mL and

Campylobacter fetus fetus 1×10^8 orgs/mL.

Preservative: 0.1mg/mL Thiomersal.

For use as an aid in control of reproductive losses (including abortions) due to *Campylobacter* infections in sheep.

Add ewe and lamb image

Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 4 of 11
Pack Sizes: 100mL, 250mL, 500mL	Date (Version Control): 05/04/2013
Description: Carton Text – Back Panel	APVMA:61563/49252
Panel labels, text above the header and below the footer are not included in this label text.	

READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT. DIRECTIONS FOR USE: USE ALL PRODUCT WITHIN 12 HOURS OF OPENING

Caution: DISCARD IF PREVIOUSLY FROZEN

Shake contents before use and keep thoroughly mixed before use.

Do not expose directly to heat and light during use. The use of an insulated container is recommended during the day to protect the vaccine. If it is to be hung beside the race, ensure it is on the shady side.

Dose:

2 mL by subcutaneous injection into the neck.

Vaccination schedule:

Unvaccinated breeding ewes should receive a sensitiser vaccination prior to joining and a booster dose a minimum of 3 weeks later. Thereafter, all breeding ewes should receive an annual booster before joining.

It is essential that ewe lambs, maiden ewes, and newly purchased breeding ewes receive two vaccinations before introduction to the breeding flock.

Whole flock vaccination is recommended.

WITHHOLDING PERIOD: Meat: NIL Milk: NIL Wool: NIL

TRADE ADVICE: Export Slaughter Interval (ESI): ESI not required.

FIRST AID:

If poisoning occurs, contact a doctor or Poisons Information Centre. Australia Phone 131 126.

USER SAFETY INFORMATION: Extreme caution should be used when injecting oil emulsion vaccines to avoid injecting yourself. Accidental self-inoculation may cause inflammatory reactions or allergic response which requires correct medical management. Medical advice should be sought as soon as possible in the event of self inoculation. Do not splash in eyes. Rinse off skin and eyes with water. Keep out of reach of children.

Additional information is listed in the material safety data sheet.

COOPERS ANIMAL HEALTH (INTERVET AUSTRALIA PTY LIMITED) 91 – 105 Harpin Street BENDIGO EAST, VIC 3550 Customer Service Ph: 1800 226 511 Fax: 1800 810 511

DISPOSAL: Dispose of empty container by wrapping in paper and putting in garbage.

Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 5 of 11
Pack Sizes: 100mL, 250mL, 500mL	Date (Version Control): 05/04/2013
Description: Carton Text – Back Panel	APVMA:61563/49252
Panel labels, text above the header and below the footer are not included in this label text.	

STORAGE: Store at 2°C to 8°C (Refrigerate. Do not freeze).

APVMA Approval No.: 61563/49252

Batch: Expiry: REFER TO BATCH AND EXPIRY ON TOP PANEL

Barcode 9322839022055

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Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 6 of 11
Pack Sizes: 100mL, 250mL, 500mL	Date (Version Control): 05/04/2013
Description: Carton Text - Top Panel	APVMA:61563/49252
Panel labels, text above the header and below the footer are not included in this label text.	

Coopers Ovilis CampyVax^{**} – Campylobacter *Vaccine for Sheep*

ACTIVE CONSTITUENTS:

Inactivated whole cell preparations of Campylobacter jejuni 1 x 10⁸ orgs/mL and

Campylobacter fetus fetus 1×10^8 orgs/mL.

Preservative: 0.1mg/mL Thiomersal.

For use as an aid in control of reproductive losses (including abortions) due to *Campylobacter* infections in sheep.

Registered Product Name: Coopers Ovilis CampyVax- Campylobacter Vaccine for Sheep	Page 7 of 11
Pack Sizes: 100mL, 250mL, 500mL	Date (Version Control): 05/04/2013
Description: Carton Text – Bottom Panel	APVMA:61563/49252
Panel labels, text above the header and below the footer are not included in this label text.	

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Coopers Ovilis CampyVax[™] –Campylobacter Vaccine for Sheep

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Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 8 of 11
Pack Sizes: 100mL, 250mL and 500mL	Date (Version Control): 05/04/2013
Description: LEAFLET	APVMA:61563/49252
Panel labels, text above the header and below the footer are not included in this label text.	

FOR ANIMAL TREATMENT ONLY

Coopers Ovilis CampyVax[™] –Campylobacter Vaccine for Sheep

ACTIVE CONSTITUENTS:

Campylabacter jejuni1 x 108 orgs/mLCampylabacter fetus fetus1 x 108 orgs/mLContains 0.1 mg/mL thiomersal as preservative

For use as an aid in control of reproductive losses (including abortions) due to *Campylobacter* infections in sheep.

DIRECTIONS FOR USE

USE ALL PRODUCT WITHIN 12 HOURS OF OPENING

Caution: DISCARD IF PREVIOUSLY FROZEN

Shake contents before use and keep thoroughly mixed before use.

Do not expose directly to heat and light during use. The use of an insulated container is recommended during the day to protect the vaccine. If it is to be hung beside the race, ensure it is on the shady side.

Contraindication:

Not for use in ewes which are severely debilitated or stressed.

Precautions:

Coopers Ovilis CampyVax[™] Campylobacter Vaccine for Sheep will not protect against abortion due to causes <u>other than</u> Campylabacter fetus fetus and Campylabacter jejuni.

Campylobacteriosis:

Campylobacteriosis (Vibriosis) in sheep is characterised clinically by abortion in late pregnant ewes and the birth of stillborn or small, weak, non-viable lambs. Lambs born alive often fail to thrive and die in the perinatal period. Campylobacteriosis can have devastating effects on the production of a sheep flock with up to 50% of ewes aborting in unvaccinated flocks that have never been exposed to the bacterial infection, experiencing an abortion storm.

Two *Campylabacter* organisms have been isolated from submitted aborted foetuses. These are *Campylobacter fetus fetus* and *Campylobacter jejuni*. *C. fetus fetus* tends to reside in the uterus of the ewe whereas *C jejuni* can reside in the gut and in the uterus.

Coopers Ovilis CampyVax[™] Campylobacter Vaccine for Sheep is an inactivated bivalent vaccine containing antigens of both *Campylabacter fetus fetus* and *Campylobacter jejuni*. These antigens were derived from strains isolated from Australian sheep. Use of the vaccine in Australian sheep flocks will help reduce reproductive losses (including abortions) due to *Campylabacter* infections in sheep

Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 9 of 11
Pack Sizes: 100mL, 250mL and 500mL	Date (Version Control): 05/04/2013
Description: LEAFLET	APVMA:61563/49252
Panel labels, text above the header and below the footer are not included in this label text.	

Dose:

2 mL by subcutaneous injection into the neck.

Vaccination schedule:

Unvaccinated breeding ewes should receive a sensitiser vaccination prior to joining and a booster dose a minimum of 3 weeks later. Thereafter, all breeding ewes should receive an annual booster before joining.

It is essential that ewe lambs, maiden ewes, and newly purchased breeding ewes receive two vaccinations before introduction to the breeding flock.

Whole flock vaccination is recommended.

Use during pregnancy:

This vaccine has been shown to be safe and efficacious in pregnant ewes. Minimise stress when handling pregnant ewes.

VACCINATION PROCEDURE

CAUTION: AVOID CARCASS DAMAGE:

- 1. Sterilise needles by boiling for at least ten minutes before use. Flush vaccinator with cooled, boiled water. Avoid use of strong disinfectants on needles and vaccinator.
- 2. Maintain maximum cleanliness at all times.
- 3. Keep needles sharp and clean. Change needles frequently (every 20-30 animals). Use short needles. Recommend maximum sizes 15mm x 18 gauge for sheep and lambs.
- 4. Check that the equipment is functioning properly and that it is delivering the correct dose.
- 5. As far as possible avoid injection of animals in wet weather or under dusty conditions.
- 6. Inject only under the skin, but not into the muscle, by raising a fold of skin and injecting the dose under the raised skin **NOT INTO IT.**
- 7. Sheep should be injected high on the side of the neck, behind the ear.

Assembly of Ovilis CampyVax and draw-off set:

- 1. Attach end of draw-off tube to the vaccinating gun.
- 2. Insert neck of Ovilis CampyVax bottle into the small diameter hole of the bottle cradle
- 3. Move the large diameter hole of the bottle cradle over the main body of the Ovilis CampyVax bottle locking the bottle into position.
- 4. Pierce rubber bung of Ovilis CampVax pack with draw-off needle, ensuring that plastic overcap snaps into position on the Ovilis CampyVax.
- 5. The plastic cord is provided for hanging Ovilis CampyVax in a convenient position e.g. from neck, belt or rail.

Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 10 of 11
Pack Sizes: 100mL, 250mL and 500mL	Date (Version Control): 05/04/2013
Description: LEAFLET	APVMA:61563/49252
Panel labels, text above the header and below the footer are not included in this label text.	

Warnings:

Syringes and needles should be sterilised before use and the injection should be made through an area of clean, dry skin, taking precautions against contamination. Careful subcutaneous vaccination technique is important.

Adverse Reactions and Side-effects:

A minor vaccination site reaction may be seen in a small percentage of vaccinated animals, this reaction will normally resolve within a few weeks, without treatment.

As with any vaccine occasional hypersensitivity reactions may occur in animals. In such cases appropriate treatment such as adrenalin or antihistamine should be administered without delay. Seek veterinary advice.

WITHHOLDING PERIOD: Meat: NIL

Milk: NIL Wool: NIL

TRADE ADVICE: EXPORT SLAUGHTER INTERVAL (ESI): ESI not required.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. *Phone Australia 131 126*. Additional information is listed in the Material Safety Data Sheet.

STORAGE:

Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. **KEEP OUT OF REACH OF CHILDREN.**

DISPOSAL:

Dispose of empty container by wrapping and putting in garbage.

Further Information:

In any animal population there may be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon correct storage and administration of the vaccine together with the animal's ability to respond. This can be influenced by such factors as genetic constitution, inter-current infection, age, nutritional status, concurrent drug therapy and stress.

Warranty

Intervet Australia Pty Limited (IAPL) known as Coopers Animal Health, warrants that this product is of merchantable quality and fit for its intended purpose. IAPL's liability for any loss, including consequential losses or injury caused by any act or omission, including negligent acts or omissions, by IAPL or its agent, is limited to replacing or repairing the product at the option of IAPL. If possible, a sample of any product causing concern should be retained or delivered to IAPL within 30 days for a scientific examination.

For further information contact Coopers Customer Service on 1800 226 511.

Registered Product Name: Coopers Ovilis CampyVax TM – Campylobacter Vaccine for Sheep	Page 11 of 11
Pack Sizes: 100mL, 250mL and 500mL	Date (Version Control): 05/04/2013
Description: LEAFLET	APVMA:61563/49252
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APVMA Approval No.: 61563/49252

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