

Registrant:	Zoetis New Zealand Limited, 8 Mahuhu Crescent, Auckland		
Trade Name:	ULTRAVAC [®] BVD	ACVM No.:	A10730
Preparation Date:	25 August 2016	Page:	1 of 7
Comments:	Text in the header box will not appear on the final label		

BOTTLE LABEL

Main Panel

RESTRICTED VETERINARY MEDICINE
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

Ultravac[®] BVD

Vaccine

Inactivated Bovine Viral Diarrhoea Virus (BVDV) vaccine.

0.1 mg/mL Thiomersal added

READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT

Gently mix (avoid vigorous shaking as this may cause product to foam) before use and keep thoroughly mixed during use

For Subcutaneous Use Only

Dose: Cattle 2 mL

WITHHOLDING PERIODS: NIL

RVM; ACVM No A10730

Store between 2°C and 8°C (Refrigerate. Do not freeze). Protect from light.

(B) 7003-

EXPIRY
mth/yr

BOTTLE LABEL

Side Panel 1

25 [50,125,250] Doses

50 [100,250,500] mL

Zoetis New Zealand
8 Mahuhu Crescent
Auckland

[Zoetis logo]


Manager Approvals Operations
Regulation and Assurance



25 JAN 2017

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CARTON
Main Panel

RESTRICTED VETERINARY MEDICINE
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FOR ANIMAL TREATMENT ONLY

Ultravac[®] BVD
Vaccine

[Graphic]

Inactivated Bovine Viral Diarrhoea Virus (BVDV) vaccine
0.1 mg/mL Thiomersal added

For the active immunisation of cattle against Bovine Viral Diarrhoea Virus (BVDV) and protection against transplacental foetal infection and the birth of persistently infected calves.

25 [50,125,250] Doses
50 [100,250,500] mL

[Zoetis logo]

CARTON
Rear Panel

A. Single Doses

Single doses of the vaccine may be withdrawn from the pack using a sterilised hypodermic needle and syringe after disinfecting the stopper of the vaccine pack.

B. Use with Automatic Vaccinator

An automatic vaccinator may be attached to the pack as follows:

1. Remove the sterilised plastic cap and tube from the pack
2. Connect the tube to the automatic vaccinator
3. Disinfect the stopper with a suitable antiseptic, e.g. methylated spirits
4. Screw the cap on to the plastic bottle of the vaccine which will cause the needle to penetrate the stopper
5. Prime the automatic vaccinator by depressing the plunger several times and vaccine will flow to the needle

NOTE: Before attachment, used metal automatic vaccinators should be re-sterilised by taking apart and boiling in water for at least ten minutes.

Following boiling, the equipment should be allowed to cool down before reassembly and use. Be careful not to contaminate the vaccinator during re-assembly.



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RESEALING

A partially used pack can be stored and used for up to 30 days after first opening if the following steps are taken:

1. Unscrew the delivery tube from the vaccine pack
2. Empty the delivery tube and vaccinator by depressing the plunger several times
3. Disinfect the stopper with a suitable antiseptic, e.g. methylated spirits

Place the vaccine pack in the original outer packaging and store upright in the refrigerator. Do not freeze

DATE FIRST OPENED:.....

CARTON **Side Panel 1**

Ultravac[®] BVD

Vaccine 50 [100, 250, 500]mL

READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT **DIRECTIONS FOR USE**

Contents must be left in outer package until immediately before use

Gently mix (avoid vigorous shaking as this may cause product to foam) before use and keep thoroughly mixed during use

For Subcutaneous Use Only

This product can be stored and used for up to 30 days after first opening

Handle aseptically and store refrigerated and protected from light

Please refer to the resealing section and the product insert for further information on storage and handling after opening.

When not in use during any given vaccination session, keep the vaccine out of direct sunlight and as cool as possible. Do not leave exposed to light or at high temperatures for long periods. Ideally, place the vaccine pack into this original cardboard carton and place in either a chillybin with an icebrick or in a refrigerator.

Dose: Cattle 2 mL

WITHHOLDING PERIODS: NIL

Disposal: Dispose of empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.



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CARTON
Side Panel 2

Ultravac® BVD
Vaccine 50 [100, 250, 500] mL

Restricted Veterinary Medicine

Registered pursuant to the ACVM Act 1997 No. A10730
See www.foodsafety.govt.nz for registration conditions
Registered to Zoetis New Zealand Ltd
8 Mahuhu Crescent, Auckland
Technical Services 0800 650 277
www.zoetis.co.nz

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CARTON
Top Flap

Ultravac® BVD
Vaccine

Store between 2°C and 8°C (Refrigerate. Do not freeze). Protect from light.

(B) 7003-
EXPIRY
mth/yr

25 [50,125,250] Doses
50 [100, 250, 500] mL

CARTON
Bottom Flap

Ultravac® BVD
Vaccine

25 [50,125,250] Doses
50 [100, 250, 500] mL



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LEAFLET

**RESTRICTED VETERINARY MEDICINE
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY**

Ultravac® BVD Vaccine

Ultravac BVD is an inactivated Bovine Viral Diarrhoea Virus (BVDV) vaccine with immunostimulating complex. 0.1 mg/ml Thiomersal is added as a preservative

For the active immunisation of cattle against Bovine Viral Diarrhoea Virus (BVDV) and protection against transplacental foetal infection and the birth of persistently infected calves.

Ultravac BVD is an orange/pink aqueous suspension. Each batch of vaccine has been fully tested before issue, ensuring that it conforms to accepted standards of potency, sterility and safety.

INDICATIONS FOR USE

Ultravac BVD can be used in both infected and non-infected herds for the routine immunisation of all classes and all ages of cattle, including breeding and pregnant cows, against infection with BVDV.

BVDV is responsible for a number of herd health problems in beef and dairy herds including reproductive loss, infertility, abortions, birth defects, mucosal disease, ill-thrift in young cattle and immunosuppression.

Multiple strains of pestivirus may be found to affect cattle. Ultravac BVD has demonstrated cross neutralisation of a range of New Zealand pestivirus isolates.

In a New Zealand foetal protection study, under strong challenge conditions at 6 months post vaccination, Ultravac BVD prevented foetal infection in 71% of heifers compared to 63% for a reference vaccine. Both vaccines demonstrated a significant reduction in the proportion of foetuses testing positive compared to the negative control group ($p < 0.002$).

DIRECTIONS FOR USE

Precautions

Following vaccination with this product, a transient febrile response in animals may be observed.

This product can be stored and used for up to 30 days after first opening. On each subsequent reuse, swab the opening with a suitable disinfectant (for example, methylated spirits) both before and after using. A sterile needle and syringe must be used each time product is removed.

Store unused material upright, at 2°C to 8°C (refrigerated) and in the original cardboard packaging to protect from light.



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Side Effects

Some swelling may develop at the site of vaccination, which may last for several weeks before gradually subsiding.

Dosage and Administration:

It is important that the vaccine is gently mixed before use and kept thoroughly mixed during use. Avoid vigorous shaking, as this may cause the product to foam.

The dose on all occasions is 2 mL injected subcutaneously (under the skin).

RECOMMENDED VACCINATION SCHEDULE

Primary vaccination

The primary course consists of a sensitiser dose followed by a booster dose at least 4 weeks, and up to 6 months, later. Immunity does not develop until at least 14 days after the second dose.

Annual revaccination

An annual booster dose of vaccine should be administered.

Breeding cattle

In breeding cattle the booster dose should be given 2-4 weeks prior to mating, to maintain an adequate level of immunity during pregnancy.

Vaccination of calves

Calves can be vaccinated with two doses from 3 months of age, followed by a pre-mating booster. When vaccinated in the presence of maternal antibodies, calves will demonstrate a strong anamnestic response after a booster dose administered 12 months later.

Vaccination of introduced stock

Introduced stock should be given the primary course of vaccination on arrival. Breeding bulls should be confirmed BVDV free and vaccinated before joining.

CAUTION AVOID CARCASE DAMAGE

1. Sterilise all injection apparatus by boiling in water for 10 minutes (or equivalent) before use. Avoid use of strong disinfectants on apparatus.
2. Maintain cleanliness at all times during vaccination. Great care must be taken to avoid contamination of the vaccine, needle and internal parts of the syringe by contact with unsterile surfaces or unwashed hands.
3. Keep needles sharp and clean. Replace frequently.
4. Use the shortest possible needle, not exceeding 15 mm in length.
5. As far as possible avoid injection of animals during wet weather or under dusty conditions.
6. This product must be injected only under the skin (subcutaneously).
7. If possible inject high on the neck behind the ear, i.e. under the skin on the side of the neck (just behind and below the base of the ear). Do not inject at any other site.

WITHHOLDING PERIODS: NIL



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FIRST AID

If poisoning occurs, contact a doctor or the Poisons Information Centre, 0800 POISON (0800 764 766).

This material may cause a mild allergic reaction in sensitive individuals on skin contact. Avoid skin contact. If skin contact occurs, remove contaminated clothing and flush skin and hair with running water. If splashed in eyes, wash out immediately with water.

STORAGE

Store between 2°C and 8°C (Refrigerate. Do not freeze). Protect from light.

DISPOSAL

Dispose of empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.

NOTE

This vaccine has been fully tested for sterility and safety before issue but it must be stressed that the correct vaccination procedure in the field is equally important if secondary infection is to be prevented. Very occasionally pathogenic organisms lying dormant in the animal's tissues are activated at the time of vaccination. This may lead to losses of stock but fortunately is of rare occurrence. As the above factors are beyond the control of the manufacturer except to the extent of any liability imposed by statute law without right of exclusion, Zoetis cannot accept responsibility for any disability or loss of stock following vaccination in respect of failure to use the correct vaccination procedure described on the label or disability or loss to any animal caused by the product.

Restricted Veterinary Medicine

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See www.foodsafety.govt.nz for registration conditions.

Approved pursuant to the HSNO Act 1996, Code No. HSR000015

See www.epa.govt.nz for approval conditions

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