

PRODUCT NAME: Improvac™ Boar Taint Vaccine for Male Pigs	PAGE: 1 OF 11
DESCRIPTION: Cartons: 100 mL, 500 mL; labels: 100 mL, 500 mL; leaflet	APVMA FILE NO: 50113 ACVM NO: 7723
PRODUCT CODES: C08888901, C08888301; 08888900, 08888300; 08889800	VERSIONS: D,D; D,D; D
NOTES: proposed cartons, labels and leaflet	DATE: 18/4/2006

Text contained within [] represents alternative pack sizes
Text contained above this line does not appear on labelling

Labels

**PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS
FOR ANIMAL TREATMENT ONLY**

Improvac™

Boar Taint Vaccine for Male Pigs

200 µg GnRF-protein conjugate per mL 0.1 mg/mL Thiomersal added

For the control of boar taint in intact male pigs

READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT

For Subcutaneous Use Only Dose: 2 mL

WITHHOLDING PERIOD NIL

CAUTION: Accidental self-injection may affect fertility in both men and women, and pregnancy. Not to be used by women of child bearing age. Care should be taken to avoid accidental self-injection and needle-stick injury when administering this product. In the event of accidental self-injection, seek medical advice immediately.

P.A.R Class I ACVM No. A7723 APVMA No. 50113/1[2]/__06

50 [250]

Doses

100 [500] mL Store at 2° to 8°C (Refrigerate. Do not freeze). Protect from light.

Pfizer logo

(B) 7888-

EXPIRY

mth/yr

Maree Zinzley
MAREE ZINZLEY
Programme Manager
(ACVM & Non-Food Products)



(item number and version)

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Cartons

Main Panel:

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Picture

**Improvac™
Boar Taint Vaccine for Male Pigs**

200 µg GnRF-protein conjugate per mL
0.1 mg/mL Thiomersal added

50 [250] Doses
100 [500] mL

For the production of heavier entire male pigs with improved meat quality through the control of boar taint; for behavioural modification which may be evidenced by increased weight gain in peripubertal male pigs during the post-vaccination preslaughter period. This increased weight gain may also result in increased fat deposition.

Pfizer logo

Side Panel 1:

**Improvac™
Boar Taint Vaccine for Male Pigs 100 [500] mL**

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

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 an esky with an icebrick or in a refrigerator.



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Contents should be left in outer package until immediately before use.
For Subcutaneous Use Only

Dose: 2 mL

Give two doses of vaccine to entire male pigs at an interval of at least 4 weeks apart. The second dose should be given 4 to 5 weeks prior to slaughter.

WITHHOLDING PERIOD NIL

SAFETY DIRECTIONS

Caution: Accidental self-injection may affect fertility in both men and women, and pregnancy. Not to be used by women of child bearing age. Care should be taken to avoid accidental self-injection and needle-stick injury when administering this product. In the event of accidental self-injection, seek medical advice immediately.

To assist the operator to avoid accidental self-injection, administration using the Pfizer Improvac™ Vaccinator, with needle safety shield, is recommended. Great care should be exercised when administering this vaccine.

Additional information is in the Material Safety Data Sheet.

Side Panel 2:

Improvac™

Boar Taint Vaccine for Male Pigs

100 [500] mL

Pfizer Animal Health
A division of Pfizer Australia Pty Ltd
38-42 Wharf Road
West Ryde NSW 2114
AUSTRALIA
Australian Technical Services Toll Free 1800 814 880
www.pfizeranimalhealth.com.au

APVMA No. 50113/1[2]/__06
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New Zealand Information

Prescription Animal Remedy (P.A.R) Class I

For use only under the authority or prescription of a veterinarian
See www.nzfsa.govt.nz/acvm for registration conditions
Registered pursuant to the ACVM Act 1997 No. A7723



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Registered to Pfizer New Zealand Limited,
14 Normanby Road, Mt Eden, Auckland
NZ Technical Services Toll Free 0800 650 277
www.pfizeranimalhealth.co.nz

**Improvac™ was jointly developed by CSL, the Victorian Institute of
Animal Science and Daratech Pty Ltd.**

(recycle logo)

(Barcode)

(item number and version)

Back 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 the Pfizer Improvac™ Vaccinator, with needle safety shield.

The Improvac™ 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 vaccinator
3. Disinfect the stopper with a suitable antiseptic eg., 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 vaccinator by depressing the plunger several times so the vaccine will flow to the needle. To prevent vaccine aerosol, conduct the priming process with the tip of the needle submerged in disinfectant.

NOTE: Before re-attachment, the Pfizer Improvac™ Vaccinator, with needle safety shield, should be re-sterilised by following the directions on the applicator pack.

Be careful not to contaminate the vaccinator during re-assembly.

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

Before re-use, the delivery tube and cap should be sterilised by boiling for at least ten minutes.

NOTE: The plastic delivery tube may become opaque

Frequent attachment of the connecting tube may cause the stopper to leak.

Therefore, the tube should not be attached



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more than twice.

Improvac™ Boar Taint Vaccine for Male Pigs is recommended for use with the Pfizer Improvac™ Vaccinator, with needle safety shield.



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End Panel 1: Improvac™

Boar Taint Vaccine for Male Pigs

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

(B) 7888-
EXPIRY
mth/yr

50 [250] Doses
100 [500] mL

End Panel 2: Improvac™

Boar Taint Vaccine for Male Pigs

50 [250] Doses
100 [500] mL



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Leaflet

**PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
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FOR ANIMAL TREATMENT ONLY**



Improvac™ Boar Taint Vaccine for Male Pigs

Improvac™ Boar Taint Vaccine for Male Pigs is prepared from an analogue of GnRF linked to a carrier protein. It is adjuvanted with a synthetic aqueous adjuvant to increase the level and duration of immunity. Each mL of vaccine provides 200 µg GnRF-protein conjugate. Thiomersal 0.1 mg/mL has been added as a preservative.

For the production of heavier entire male pigs with improved meat quality through the control of boar taint; for behavioural modification which may be evidenced by increased weight gain in peripubertal male pigs during the post-vaccination preslaughter period. This increased weight gain may also result in increased fat deposition.

INDICATIONS FOR USE

Improvac™ Boar Taint Vaccine for Male Pigs is used to control boar taint caused by the accumulation of taint substances (including androstenone and skatole) in entire male pigs. Taint substances that may already be present at the time of vaccination are rapidly metabolised allowing the entire male pig to be presented for slaughter at a heavier weight and/or older age with improved meat quality.

Through its inhibitory effect on GnRF (Gonadotropin Releasing Factor) and testosterone production, **Improvac™ Boar Taint Vaccine for Male Pigs** also modifies the behaviour of peripubertal male pigs which may be evidenced by increased weight gain during the post-vaccination preslaughter period. This increased weight gain may also result in an increase in fat deposition

DIRECTIONS FOR USE

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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Contraindications and Precautions

This product is contraindicated for use in male pig breeding stock. Inadvertent vaccination of male pig breeding stock may affect subsequent fertility

Side Effects:

Some swelling may develop at the site of vaccination, and in a small proportion of pigs, may last for several weeks before gradually subsiding.

Dosage and Administration:

The dose on all occasions, is **2 mL injected subcutaneously** (just under the skin). The recommended site for injection is at the base of the neck, immediately behind the ear.

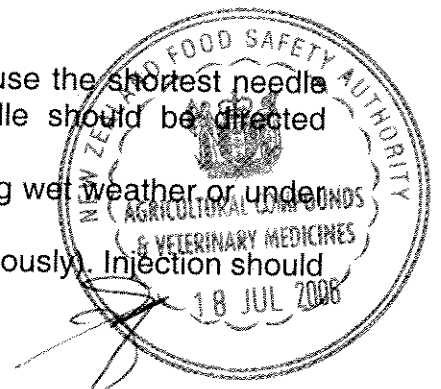
Two doses of vaccine should be administered to entire male pigs at an interval of at least 4 weeks apart. The second dose should be given 4 to 5 weeks prior to slaughter.

The above recommendations on method and timing of vaccination, and injection site, should be closely followed to ensure optimum effect and minimise carcass damage.

Effective immunity (the development of anti-GnRF antibodies) develops approximately 10 to 14 days after administration of the second dose of vaccine. The second dose of vaccine, at least 4 weeks after the first, is essential to limit the further production of taint substances. The second dose of vaccine must be given 4 to 5 weeks prior to slaughter to control taint substances already present in the carcass. Entire male pigs intended for slaughter at 26 weeks of age will therefore receive their second dose of vaccine at 21-22 weeks of age, their first dose of vaccine having been given at 17-18 weeks of age or earlier.

Caution: Avoid Carcass Damage

1. Before use, read the cleaning and operating instructions for the Pfizer Improvac™ Vaccinator.
2. Sterilise all injection apparatus by boiling in water for 10 minutes (or equivalent) before use. Avoid use of strong disinfectants on apparatus. Lubricate the vaccinator prior to use.
3. Maintain cleanliness at all times during vaccination. 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.
4. Keep needles sharp and clean. Replace frequently.
5. To avoid administering the vaccine into the neck muscles, use the shortest needle possible and not exceeding 15 mm in length. The needle should be directed perpendicular to the skin surface.
6. As far as possible, avoid injection of animals outdoors during wet weather or under dusty conditions. Avoid wet and soiled areas of skin.
7. This product must be injected only under the skin (subcutaneously). Injection should



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8. be made through an area of clean, dry skin, taking precautions against contamination. Before the vaccine is injected, the proposed site of injection through the animal's skin may be cleaned by swabbing with cotton-wool soaked in an antiseptic solution, such as methylated spirits.
9. 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 PERIOD NIL

SAFETY DIRECTIONS

Caution: Accidental self-injection may affect fertility in both men and women, and pregnancy. Not to be used by women of child bearing age. Care should be taken to avoid accidental self-injection and needle-stick injury when administering this product. In the event of accidental self-injection, seek medical advice immediately.

To assist the operator to avoid accidental self-injection, this product should be administered using the Pfizer **Improvac™** Vaccinator, with needle safety shield. Great care should be exercised when administering this vaccine.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 POISON (0800 764766).

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

Additional information is in the Material Safety Data Sheet.

GENERAL INFORMATION ON BOAR TAINT AND THIS VACCINE

Boar taint is a distinct and unpleasant, perspiration or urine-like smell, which may be detected when meat from affected entire male pigs is cooked. Taint is rarely detected in meat from either castrated males, sexually immature males, or female pigs.

There are two main compounds which contribute to boar taint; the testicular steroid, 5 α -androstene, and skatole, a metabolite of the amino-acid, tryptophan. Marked differences in the carcase level of both 5 α -androstene and skatole exist between castrated males, females and entire male pigs, with the levels in entire male pigs being significantly higher than in castrates or females.

To avoid tainting of the meat, entire male pigs destined for fresh meat consumption may be slaughtered at a relatively early age and before complete sexual maturity. Alternatively, taint



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may be overcome by castration of the male pig before weaning.

Improvac™ Boar Taint Vaccine for Male Pigs works to inhibit GnRF activity and testosterone production, and thereby reduces both the production and accumulation of tainting substances. Any tainting substances that are already present in the carcass are then rapidly metabolised. The entire male pig may be presented for slaughter, having benefited from the effects of its own testicular steroids on growth and carcass composition for the majority of its production life.

Through this inhibitory effect on testosterone production, **Improvac™ Boar Taint Vaccine for Male Pigs** also works to modify the behaviour of peripubertal male pigs, reducing aggressive behaviour. Some field studies have demonstrated improved weight gain and increased P2 fat thickness in peripubertal male pigs as a result of this effect.

Uncommonly, environmental sources of skatole can also contribute to taint, equally affecting females, castrates and entire male pigs. The major predisposing factor to this is absorption of skatole through the skin in a wet and soiled environment. Certain feedstuffs have also been implicated as a source of high skatole levels in the carcass. The use of **Improvac™ Boar Taint Vaccine for Male Pigs** cannot counter this uncommon event.

MODE OF ISSUE

Improvac™ Boar Taint Vaccine for Male Pigs is available in 100 and 500 mL plastic multidose containers.

STORAGE

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

DISPOSAL

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



Improvac™ Boar Taint Vaccine for Male Pigs was jointly developed by CSL, the Victorian Institute of Animal Science and Daratech Pty Ltd.

NOTE

This vaccine has been fully tested for potency, 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 from the animals' skin or lying dormant in the animals' tissues are activated at the time of vaccination and are able to initiate a local infection at the site of injection. 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, Pfizer cannot accept responsibility for any disability or loss of stock following vaccination in respect of failure

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to use the correct vaccination procedure described on the label, or disability or loss to any animal caused by the product.

APVMA Approval Number 50113/1204
Australian Technical Services Toll Free 1800 814 883
www.pfizeranimalhealth.com.au

New Zealand Information

Prescription Animal Remedy (P.A.R) Class I

For use only under the authority or prescription of a veterinarian

Registered pursuant to the ACVM Act 1997, No A7723

See www.nzfsa.govt.nz/acvm for registration conditions

Registered to Pfizer New Zealand Limited,

14 Normanby Road, Mt Eden, Auckland

NZ Technical Services Toll-Free 0800 650 277

www.pfizeranimalhealth.co.nz

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April, 2006

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