



Product Name: PORCILIS PCV IDAL EMULSION FOR INJECTION FOR PIGS
APVMA Approval No: 84901/139267

Label Name:	PORCILIS PCV IDAL EMULSION FOR INJECTION FOR PIGS
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Signal Headings:	FOR ANIMAL TREATMENT ONLY
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Constituent Statements:	<p>Each dose of 0.2 mL contains: Porcine circovirus type 2 (PCV2) ORF 2 subunit antigen: ≥ 1436 AU*. * Antigenic units as determined in the in vitro potency test (antigenic mass assay).</p> <p>Also contains (adjuvants): 8.3 mg Light liquid paraffin 0.6 mg dl-α-tocopheryl acetate</p>
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Claims:	<p>For the active immunisation of pigs against PCV2 infection. To reduce PCV2 associated viraemia, virus load in lungs, tonsils and lymphoid tissues. To reduce shedding caused by PCV2 infection, and thereby minimise environmental contamination. To reduce weight loss and mortality associated with PCV2 infection.</p> <p>Onset of immunity: 2 weeks after vaccination. Duration of immunity: 23 weeks after vaccination.</p> <p>Porcilis PCV IDAL is effective in the presence of maternally derived antibodies to PCV2.</p>
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Net Contents:	10x10mL 10x20mL 1x10mL 1x20mL
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Directions for Use:	
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Restrains:	DO NOT MIX with any other veterinary medicinal product, except Porcilis Lawsonia IDAL Inactivated Vaccine for Pigs (APVMA No. 91825).
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Contraindications:	
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Precautions:	Safety studies to support use of the product during first 17 days of pregnancy and in breeding males have not been conducted.
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Side Effects:	Transient local reactions are common and usually consist of a hard non-painful swelling of up to 2 cm diameter. Occasionally the swellings may increase up to 6.5 cm diameter and may be associated with redness and/or scabs. The local reactions disappear completely within approximately 7 weeks after vaccination.
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Dosage and Administration:	<p>Before use allow the vaccine to reach room temperature. Shake well before use. Use the entire contents within 8 hours of opening.</p> <p>FOR INTRADERMAL USE ONLY.</p> <p>Vaccinate healthy animals only.</p> <p>Intradermal administration of 0.2 mL per animal, preferably at the sides of the neck, along the muscles of the back or in the hind leg (all pigs) or perianal area (in pigs for reproduction) using the multi-dose needle-free IDAL device for intradermal application of liquids suitable to deliver a 'jet-stream' volume of vaccine (0.2mL ± 10%) through the epidermal layers of the skin. Safety and efficacy of Porcilis PCV IDAL have been demonstrated using the IDAL device.</p> <p>Vaccination scheme Vaccinate once from an age of 3 weeks onwards and re-vaccination at 23 weeks interval is recommended.</p> <p>Mixed use with Porcilis Lawsonia IDAL Inactivated Vaccine for Pigs (APVMA no. 91825).</p> <p>Porcilis PCV IDAL may be used to reconstitute Porcilis Lawsonia IDAL freeze-dried pellet shortly before vaccination in pigs from 3 weeks of age onwards as follows (see attached table):</p> <p>For proper reconstitution and correct administration, use the following procedure:</p> <ol style="list-style-type: none"> 1. Allow Porcilis PCV IDAL to reach room temperature and shake well before use. 2. Add approximately 5-10 mL of Porcilis PCV IDAL to the Porcilis Lawsonia IDAL freeze-dried pellet and mix briefly. 3. Withdraw the reconstituted concentrate from the vial and transfer it back into the vial with the Porcilis PCV IDAL. Shake briefly to mix. 4. Use the vaccine suspension within 6 hours of reconstitution. Any vaccine remaining at the end of this time should be discarded. <p>Dosage A single dose (0.2 mL) of Porcilis Lawsonia IDAL mixed with Porcilis PCV IDAL is given intradermally. Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking. Avoid introduction of a contamination by multiple broaching.</p> <p>This section contains file attachment.</p>
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General Directions:	<p>Porcilis PCV IDAL has been demonstrated safe in pregnant (from the 18th day of pregnancy) and lactating sows.</p> <p>Safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be mixed with Porcilis Lawsonia IDAL Inactivated Vaccine for Pigs (APVMA No. 91825). The product literature of Porcilis Lawsonia IDAL</p>
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should be consulted before administration. Adverse reactions are as described in the section Side effects, except for local injection site reactions where a maximum size of up to 7 cm may occur in individual pigs.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except Porcilis Lawsonia IDAL. 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.

Withholding Periods: Zero (0) days.

Trade Advice: EXPORT SLAUGHTER INTERVAL (ESI): Zero (0) days.

Safety Directions:

First Aid Instructions: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

First Aid Warnings:

Additional User Safety:

Take care to avoid self-injection.

This product contains emulsion adjuvants that are irritants. In the event of self-administration, it can cause significant pain and swelling at the injection site, perhaps also involving the draining lymph nodes. Medical or surgical intervention may be required. Contact a doctor immediately, even if only a very small amount is injected, and take this package leaflet/carton with you. Allow the wound to bleed freely and DO NOT squeeze or interfere with the injection site.

Ancillary advice to the medical practitioner

This product contains emulsion adjuvants. Even small amounts of self-administered emulsion can cause intense swelling and a persistent granulomatous inflammatory reaction. If injected into a finger joint or tendon sheath, the product may track along the tendon, perhaps also involving the draining lymph nodes. The swelling and inflammation may compromise blood supply and result in necrosis that, in rare cases, may lead to the loss of a digit.

Following appropriate immediate local cleansing, corticosteroids may be considered to decrease the severity of any local reaction. Ascertain the patient's tetanus immunisation status, and provide booster or primary series, as appropriate.

In some cases of self-injection, PROMPT surgical attention may be required. The wound should be incised and irrigated to remove the vaccine, especially where there is involvement of finger pulp or tendon. Complete curettage or total excision of the lesion may be required for chronic granulomatous reactions. Meticulous technique is required to stop inadvertent spread of the product.

Environmental Statements:

Disposal: Dispose of container by wrapping with paper and putting in garbage.

Storage:

Store between 2 °C and 8 °C (refrigerate, do not freeze). Protect from direct sunlight.

Dosage and Administration:

Porcilis Lawsonia IDAL freeze-dried pellet	Porcilis PCV IDAL
50 doses	10 mL
100 doses	20 mL