



Product Name: PORCILIS LAWSONIA IDAL INACTIVATED VACCINE FOR PIGS
 APVMA Approval No: 91825/133595

Label Name:	PORCILIS LAWSONIA IDAL INACTIVATED VACCINE FOR PIGS
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Signal Headings:	FOR ANIMAL TREATMENT ONLY
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Constituent Statements:	<p>[Lyophilisate] Each 0.2 mL dose of reconstituted vaccine contains Inactivated Lawsonia intracellularis strain SPAH-08: ≥ 5323 U* *Antigenic mass units as determined in the in vitro potency test (ELISA).</p> <p>[Solvent] Per 0.2 mL: 8.3 mg paraffin, light liquid (adjuvant) 0.6 mg dl-α-tocopheryl acetate (adjuvant)</p>
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Claims:	<p>For the active immunisation of pigs from 3 weeks of age to reduce diarrhoea, loss of daily weight gain, intestinal lesions, bacterial shedding and mortality caused by Lawsonia intracellularis infection.</p> <p>Onset of immunity: 4 weeks after vaccination. Duration of immunity: 21 weeks after vaccination.</p>
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Net Contents:	<p>1 x 50 doses and 1 x 10 ml solvent 1 x 100 doses and 1 x 20 ml solvent 10 x 50 doses and 10 x 10 ml solvent 10 x 100 doses and 10 x 20 ml solvent</p>
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Directions for Use:	
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Restrains:	DO NOT MIX the freeze-dried vaccine pellet with any other veterinary medicinal product, except the recommended "Solvent for Porcilis Lawsonia ID" or Porcilis PCV IDAL Emulsion for Injection for Pigs (APVMA No. 84901).
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Contraindications:	
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Precautions:	Use with caution in pregnant or lactating sows as the safety of this product has not been established.
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Side Effects:	An increase in body temperature very commonly occurs (mean 0.1°C, in individual pigs up to 1.4°C). The animals return to normal temperature within 1 day after vaccination. Local injection site reactions in the form of swelling may very commonly occur (mean diameter of approximately 1cm, in individual pigs up to 5cm). Local reactions resolve within 4 weeks after vaccination.
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Dosage and Administration:	<p>USE ALL PRODUCT WITHIN 6 HOURS OF RECONSTITUTION. Discard the unused portion.</p> <p>For intradermal administration only.</p> <p>Reconstitute the freeze-dried vaccine pellet in the solvent or Porcilis PCV IDAL Emulsion for Injection for Pigs (APVMA No. 84901) in as follows (see attached):</p> <p>For proper reconstitution and correct administration, use the following procedure:</p> <ol style="list-style-type: none"> 1. Allow the solvent or Porcilis PCV IDAL to reach room temperature and shake well before use. 2. Add approximately 5-10 mL of the solvent or Porcilis PCV IDAL to the freeze-dried vaccine pellet vial and mix briefly. 3. Withdraw the reconstituted concentrate from the vial and transfer it back into the vial with the solvent or the Porcilis PCV IDAL. Shake briefly to mix. <p>Avoid introduction of a contamination by multiple broaching.</p> <p>Vaccinate healthy animals only.</p> <p>Dosage A single dose of 0.2 mL of reconstituted vaccine in pigs starting at 3 weeks of age. Vaccinate pigs by the intradermal route using a multi-dose needle-free injection 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.</p> <p>Safety and efficacy of Porcilis Lawsonia IDAL have been demonstrated using the IDAL device.</p> <p>Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking.</p> <p>This section contains file attachment.</p>
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General Directions:	<p>Safety and efficacy data in pigs from 3 weeks of age onwards demonstrate that this vaccine can be mixed with Porcilis PCV IDAL Emulsion for Injection for Pigs (APVMA No. 84901). The product literature of Porcilis PCV IDAL should be consulted. 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 be observed in individual pigs. All local reactions resolve within 5 weeks after vaccination.</p> <p>No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except Porcilis PCV 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.</p>
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	<p>Overdose</p> <p>No adverse reactions other than the local reactions described in the section Side Effects were observed after the administration of a double dose of Porcilis Lawsonia IDAL reconstituted in solvent.</p>
Withholding Periods:	Zero (0) days.
Trade Advice:	EXPORT SLAUGHTER INTERVAL(ESI): Zero (0) days. Before using this product, confirm the current ESI from Intervet Australia Pty Limited on 1800 033 461 or the APVMA website (www.apvma.gov.au/residues).
Safety Directions:	
First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
First Aid Warnings:	
Additional User Safety:	<p>Take care to avoid self-injection.</p> <p>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.</p> <p>Ancillary advice to the medical practitioner</p> <p>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.</p> <p>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.</p> <p>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.</p>
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 light.

Freeze-dried vaccine pellet	Solvent for Porcilis Lawsonia ID or Porcilis PCV IDAL vaccine
50 doses	10 ml
100 doses	20 ml