DISPLAYED BY INFOPEST

RLP APPROVED

Product Name: PORCILIS PCV M HYO

APVMA Approval No: 82241/140074

Label Name:	PORCILIS PCV M HYO

Signal Headings:	FOR ANIMAL TREATMENT ONLY

Constituent Statements:	Each dose of 2 mL contains: Active constituents: Porcine circovirus type 2 (PCV2) ORF 2 subunit antigen: ≥ 2828 AU* Mycoplasma hyopneumoniae J strain inactivated: ≥ 2.69 RPU** Also contains (Adjuvants): 0.268 mL Light mineral Oil 1.64 - 2.40 mg Aluminium hydroxide * Antigenic units ** Relative potency units

Claims:	For the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection. To aid in the prevention of enzootic pneumonia of swine caused by *Mycoplasma hyopneumoniae.* To reduce the loss of daily weight gain during the finishing period in face of infections with *Mycoplasma hyopneumoniae* and/or PCV2 (as observed in field studies). Onset of immunity with single dose vaccination PCV2: 2 weeks after vaccination. *M. hyopneumoniae*: 4 weeks after vaccination. Onset of immunity with two dose vaccination PCV2: 18 days after first vaccination. *M. hyopneumoniae*: 3 weeks after the second vaccination. Duration of immunity (single and flexible vaccination schedules) PCV2: 22 weeks after (the last) vaccination. *M. hyopneumoniae*: 21 weeks after (the last) vaccination

Net Contents:	20 mL, 50 mL, 100 mL, 200 mL, 500 mL

	[10x] 20 mL, 50 mL, 100 mL, 200 mL, 500 mL

Directions for Use:	

Restraints:	DO NOT mix with any other vaccine or immunobiological product, except Porcilis Lawsonia Inactivated Vaccine for Pigs (APVMA No. 91351).

Contraindications:	

Precautions:	Use with caution in pregnant or lactating sows as the safety of this product has not been determined.

Side Effects:	In laboratory and field trials: A transient increase in body temperature very commonly occurs on the day of vaccination. This resolves spontaneously after 1 to 2 days without treatment. Mild systemic reactions may uncommonly be observed up to one day after vaccination. Affected animals are less active, show a tendency to lie down and display minor signs of discomfort. In rare cases a hypersensitivity-like reaction may be observed after the first vaccination of the 2x1 mL dose vaccination schedule. Transient local injection site reactions, which are restricted to a slight swelling (<2 cm diameter), may uncommonly occur and normally disappear within 3 days after completion of the vaccination schedule. In field use (with single dose vaccination): In very rare cases anaphylactic-type reactions can occur, which may be life-threatening. In the event of such reactions, treatment may be needed.

Dosage and Administration:	Shake well before use. Use all product within 3 days of opening. For mixed use with Porcilis Lawsonia Inactivated Vaccine for Pigs (APVMA No. 91351) - use all product within 6 hours of reconstitution. Discard the unused portion. Vaccinate only healthy animals. The vaccine is a liquid and ready to use product. Before using the vaccine, allow it to reach room temperature (15-25 °C) and shake well before use. Use sterile syringes and needles. Avoid introduction of contamination. Vaccinate pigs by the intramuscular route in the neck. Flexible vaccination schedule Option 1. Single dose (2 mL): A single dose of 2 mL from 3 weeks of age. Option 2. Two doses (2x1 mL): Two 1 mL doses from a minimum of 3 days of age with an interval of at least 18 days between doses. When PCV2 and/or M. hyopneumoniae infections occur early, the two dose vaccination schedule is recommended. Mixed use with Porcilis Lawsonia (APVMA No. 91351).

	The Porcilis PCV M Hyo emulsion may be used to reconstitute Porcilis Lawsonia freeze-dried vaccine pellet shortly before vaccination in pigs from 3 weeks of age onwards as follows (see attached): For proper reconstitution and correct administration, use the following procedure: 1. Allow Porcilis PCV M Hyo to reach room temperature and shake well before use. 2. Add 5-10 mL Porcilis PCV M Hyo to the Porcilis Lawsonia freeze-dried vaccine pellet and mix briefly. 3. Withdraw the reconstituted concentrate from the vial and inject it back into the vial with Porcilis PCV M Hyo. Shake briefly to mix. Dosage A single dose (2 mL) of Porcilis Lawsonia mixed with Porcilis PCV M Hyo is given intramuscularly in the neck. Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking. This section contains file attachment.

General Directions:	Safety and efficacy data in pigs from 3 weeks of age onwards demonstrate that this vaccine can be mixed with Porcilis Lawsonia Inactivated Vaccine for Pigs (APVMA No. 91351) and given at the same time. The product literature of Porcilis Lawsonia should be consulted before administration. Adverse reactions are as described in the section Side effects.

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. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.

Storage:	Store between 2 °C and 8 °C (refrigerate, do not freeze). Protect from light.

Dosage and Administration:

Porcilis Lawsonia freeze-dried pellet	Porcilis PCV M Hyo
50 doses	100 mL
100 doses	200 mL