

Product Name: PORCILIS PCV VACCINE
APVMA Approval No: 64025/131495



Label Name:	PORCILIS PCV VACCINE
-------------	----------------------

Signal Headings:	FOR ANIMAL TREATMENT ONLY
------------------	---------------------------

Constituent Statements:	<p>Porcine Circovirus Type 2 ORF2 subunit antigen: ≥ 3720 AU per dose of 2 mL.</p> <p>Also contains 346 mg light liquid paraffin (adjuvant) 25 mg dl-α-tocopheryl acetate (adjuvant)</p>
-------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Claims:	<p>For active immunisation of pigs to reduce the virus load in blood and lymphoid tissues and to reduce mortality and weight loss associated with Porcine circovirus type 2 related infection (PCVD) occurring during the fattening period.</p> <p>Onset of immunity: 2 weeks. Duration of immunity: 22 weeks.</p> <p>A single dose breaks through up to medium levels of maternally derived antibodies in piglets. A double dose breaks through medium to high levels of maternally derived antibodies.</p>
---------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Net Contents:	<p>1 x 20 mL (10 doses) 5 x 20 mL (50 doses) 10 x 20 mL (100 doses) 1 x 50 mL (25 doses) 1 x 100 mL (50 doses) 1 x 200 mL (100 doses) 1 x 500 mL (250 doses)</p>
---------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Directions for Use:	
---------------------	--

Restrains:	DO NOT mix with any other vaccine or immunological product.
------------	-------------------------------------------------------------

Contraindications:	
--------------------	--

Precautions:	
Side Effects:	<p>In laboratory studies and field trials: A transient rise in body temperature may occur until 2 days after vaccination. Some piglets may be depressed and show a reduced feed intake for up to 5 days. A transient local reaction at the injection site may be observed in the form of a hard and sometimes warm swelling (up to a diameter of 7cm) diminishing over a period of approximately 14-21 days. A hypersensitivity-like reaction may occur; the animals will recover in several minutes without further treatment.</p> <p>In post marketing experience: In very rare cases anaphylactic-type reactions can occur, which may be life-threatening. In the event of such reactions, treatment may be needed.</p>
Dosage and Administration:	<p>Shake well before use. Use the entire contents within 8 hours of opening.</p> <p>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. Avoid use of vaccination equipment with rubber parts.</p> <p>Administer one dose (2 mL) by intramuscular injection in the neck in the area behind the ear, according to the following schedule:</p> <p>Vaccination schedule In the case of low to medium levels of maternally derived antibodies against PCV-2 a single vaccination (2 mL) to pigs from 3 weeks of age.</p> <p>When higher levels of maternally derived PCV-2 antibodies are expected, the following schedule of two vaccinations is advised: the first injection (2 mL) can be given from an age of 3-5 days, the second injection (2 mL) 2-3 weeks later.</p>
General Directions:	<p>DRUG INTERACTIONS: Compatibility studies with concurrent use of other veterinary products were not performed.</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 13 11 26.
First Aid Warnings:	
Additional User Safety:	<p>Take care to avoid self-injection.</p> <p>This product contains mineral oil. In the event of self-administration, seek prompt medical attention and take this package leaflet/carton with you. Accidental self-administration may</p>

result in local bruising, severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision of the injected area, especially where there is involvement of finger pulp or tendon.

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.