

Product Name: Porcilis Lawsonia Inactivated Vaccine for Pigs  
APVMA Approval No: 91351/131935



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| Label Name: | Porcilis Lawsonia Inactivated Vaccine for Pigs |
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| Signal Headings: | FOR ANIMAL TREATMENT ONLY |
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| Constituent Statements: | <p>[Lyophilisate]<br/>Each 2 mL dose of reconstituted vaccine contains<br/>Inactivated Lawsonia intracellularis strain SPAH-08: <math>\geq 5323</math> U*</p> <p>*Antigenic mass units as determined in the in vitro potency test (ELISA).</p> <p>[Solvent]<br/>Per 2 mL<br/>222.4 mg Light mineral oil (adjuvant)<br/>2.0 mg Aluminium (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.<br/>Duration of immunity: 21 weeks after vaccination.</p> |
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| Net Contents: | <p>1 x 50 doses and 1 x 100 mL solvent<br/>1 x 100 doses and 1 x 200 mL solvent<br/>10 x 50 doses and 10 x 100 mL solvent<br/>10 x 100 doses and 10 x 200 mL solvent</p> |
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| Directions for Use: |  |
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| Restrains: | <p>DO NOT MIX the freeze-dried vaccine pellet with any other veterinary medicinal product, except the recommended "Solvent for Porcilis Lawsonia" or Porcilis PCV M Hyo (APVMA No. 82241).</p> |
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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 0.6°C, in individual pigs up to 1.3°C). The animals return to normal temperature within 1 day after vaccination. Local injection site reactions in the form of swelling (< 5 cm diameter) may commonly occur and resolve within 23 days. Anorexia and lethargy have been reported uncommonly. |
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| Dosage and Administration:  | <p>USE ALL PRODUCT WITHIN 6 HOURS OF RECONSTITUTION. Discard the unused portion.</p> <p>Intramuscular use.</p> <p>Reconstitute the freeze-dried vaccine pellet in the solvent or in Porcilis PCV M Hyo (APVMA No. 82241) as follows:</p> <table border="1"> <thead> <tr> <th>Freeze-dried vaccine pellet</th> <th>Solvent or Porcilis PCV M Hyo</th> </tr> </thead> <tbody> <tr> <td>50 doses</td> <td>100 mL</td> </tr> <tr> <td>100 doses</td> <td>200 mL</td> </tr> </tbody> </table> <p>For proper reconstitution and correct administration, use the following procedure:</p> <ol style="list-style-type: none"> <li>1. Allow the solvent or Porcilis PCV M Hyo to reach room temperature and shake well before use.</li> <li>2. Add 5-10 mL of the solvent or Porcilis PCV M Hyo to the freeze-dried vaccine pellet and mix briefly.</li> <li>3. Withdraw the reconstituted concentrate from the vial and transfer it back into the vial with the solvent or the Porcilis PCV M Hyo. Shake briefly to mix.</li> </ol> <p>Needle length and diameter should be adapted to the age of the animal. Avoid introduction of a contamination by multiple broaching.</p> <p>Vaccinate healthy animals only.</p> <p>Dosage<br/>A single dose of 2 mL of reconstituted vaccine in pigs starting at 3 weeks of age. Vaccinate pigs by the intramuscular route in the neck.</p> <p>Visual appearance after reconstitution: homogenous white to nearly white emulsion after shaking.</p> | Freeze-dried vaccine pellet | Solvent or Porcilis PCV M Hyo | 50 doses | 100 mL | 100 doses | 200 mL |
|-----------------------------|---|-----------------------------|-------------------------------|----------|--------|-----------|--------|
| Freeze-dried vaccine pellet | Solvent or Porcilis PCV M Hyo   |                             |                               |          |        |           |        |
| 50 doses                    | 100 mL  |                             |                               |          |        |           |        |
| 100 doses                   | 200 mL  |                             |                               |          |        |           |        |

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| General Directions: | <p>Safety and efficacy data in pigs from 3 weeks of age onwards are available, which demonstrate that this vaccine can be given at the same time with Porcilis PCV M Hyo (APVMA No. 82241). When Porcilis Lawsonia is given at the same time with Porcilis PCV M Hyo, these products should be mixed. The product literature of Porcilis PCV M Hyo should be consulted before administration. An increase in body temperature very commonly occurs (mean 1.0°C, in individual pigs up to 2.5°C). The animals return to normal temperature within 1 day after vaccination.</p> <p>Overdose<br/>No adverse reactions other than the local reactions described in the section Side effects and the temperature increases described above were observed after the administration of a double dose of Porcilis Lawsonia reconstituted in Porcilis PCV M Hyo.</p> |
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| Withholding Periods: | Zero (0) days. |
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| 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 ( <a href="http://www.apvma.gov.au/residues">www.apvma.gov.au/residues</a> ). |
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| Safety Directions: |  |
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| First Aid Instructions: | If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126. |
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| First Aid Warnings: |  |
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| 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> |
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| Environmental Statements: |  |
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| 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. |
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| Storage: | Store between 2°C and 8°C (refrigerate, do not freeze). Protect from light. |
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