



Product Name: INGELVAC MYCOFLEX MYCOPLASMA HYOPNEUMONIAE INACTIVATED VACCINE FOR PIGS  
APVMA Approval No: 69810/135403

Label Name:	INGELVAC MYCOFLEX MYCOPLASMA HYOPNEUMONIAE INACTIVATED VACCINE FOR PIGS
Signal Headings:	KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
Constituent Statements:	Each 1 mL dose contains: INACTIVATED MYCOPLASMA HYOPNEUMONIAE $\geq$ 1.0 RP Also contains: 1mg Carbomer (Adjuvant)
Claims:	For the vaccination of healthy, susceptible swine at weaning (3 weeks of age) or older as an aid in the prevention of enzootic pneumonia of swine caused by <i>Mycoplasma hyopneumoniae</i> . This vaccine has been demonstrated to be safe in pregnant and lactating sows.
Net Contents:	10 doses - 15 mL (30 mL HSB*) 20 doses - 30 mL (60 mL HSB*) 50 doses - 60 mL (120 mL HSB*) 100 doses - 120 mL (250 mL HSB*) 250 doses - 250 mL (500 mL HSB*) *HSB = head space bottle - includes larger headspace
Directions for Use:	
Restraints:	
Contraindications:	
Precautions:	No information is available on the safety and efficacy of the concurrent use of this vaccine with any other vaccine/immunological products except with Boehringer Ingelheim's Ingelvac CircoFLEX.

Side Effects:	A mild and transient hyperthermia very commonly occurs on the day of vaccination.
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Dosage and Administration:	<p>SHAKE WELL BEFORE USE and use immediately. During use, hold vaccine at or below 25°C. Use entire contents after broaching the container.</p> <p>Administer a single 1 mL dose per pig intramuscularly.</p> <p>When mixed with Ingelvac CircoFLEX:</p> <ul style="list-style-type: none"> <li>•Vaccinate only pigs from 3 weeks of age.</li> <li>•Use the same volumes of Ingelvac CircoFLEX and Ingelvac MycoFLEX.'</li> </ul> <p>(Conventional Bottle mixing instructions):</p> <ul style="list-style-type: none"> <li>•Aseptically transfer the full content of each vaccine bottle into a pre-sterilised plastic or glass container of at least double the capacity of the vaccine bottle by using pre-sterilised transfer needles. Pre-sterilised transfer needles are commonly available via medical equipment suppliers.</li> </ul> <p>(Head Space Bottle mixing instructions):</p> <ul style="list-style-type: none"> <li>•Use a pre-sterilised transfer needle. Pre-sterilised transfer needles are commonly available via medical equipment suppliers.</li> </ul> <p>To ensure correct mixing follow the steps as described below:</p> <ul style="list-style-type: none"> <li>•Connect one end of the transfer needle to the vaccine bottle of Ingelvac MycoFLEX.</li> <li>•Connect the opposite end of the transfer needle to the vaccine bottle of Ingelvac CircoFLEX. Transfer the Ingelvac CircoFLEX vaccine into the vaccine bottle of Ingelvac MycoFLEX. If needed, gently press the vaccine bottle of Ingelvac CircoFLEX to facilitate the transfer. After the transfer of the full content of Ingelvac CircoFLEX, disconnect the transfer needle. Discard transfer needle and the empty vaccine bottle of Ingelvac CircoFLEX.</li> </ul> <p>To ensure appropriate mixing of the vaccines, gently shake the vaccine bottle until the mixture is of uniform orange to reddish colour.</p> <p>TwistPak bottle instructions:</p> <p>Step 1: Twist and remove the red base of the bottle of Ingelvac MycoFLEX to uncover the connection system. The red base can be used upside down as a stand to position the bottle upside down. Twist and remove the green base of the bottle of Ingelvac CircoFLEX</p> <p>Step 2: Rotate and align the connection ends of the two bottles until they engage</p> <p>Step 3: Firmly push the bottles together until they touch completely. A click confirms that the bottles are engaged.</p> <p>Step 4: Twist the vaccine bottles clockwise to complete the coupling of the two bottles.</p> <p>Step 5: To ensure appropriate mixing, slowly invert the locked bottles until the mixture is of uniform colour.</p> <p>(Common mixing instructions for both bottles):</p> <ul style="list-style-type: none"> <li>• During vaccination the uniformity of the coloured mixture should be monitored and maintained by continuous agitation.</li> <li>•Administer one single injection dose (2 mL) of the mixture intramuscularly per pig, irrespective of body weight. For administration, vaccine devices should be used in accordance with the device instructions provided by the manufacturer.</li> <li>•Use the entire vaccine mixture immediately after mixing.</li> </ul> <p>The package leaflet of Ingelvac CircoFLEX should also be consulted before the administration of the mixed product.</p> <p>This section contains file attachment.</p>
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General Directions:	
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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 the Boehringer Ingelheim Animal Health Australia Pty. Ltd. on 1800 808 691 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:	Take care to avoid self-injection. Accidental self-administration may result in local bruising, pain and swelling. In the event of self-administration, seek medical attention and show the package leaflet or label to the Medical Practitioner.
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Environmental Statements:	
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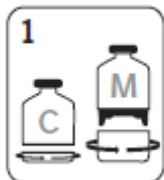
Disposal:	Dispose of container by wrapping in paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.
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Storage:	Store between 2°C and 8°C (refrigerate, do not freeze). Protect from light.
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Scan the following QR Code to access a video describing the mixing process step by step.

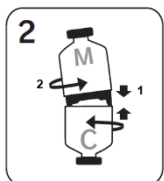


To ensure correct mixing follow the steps as described below:



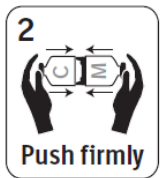
**Step 1**

**Twist and remove** the red base of the bottle of Vaccine M to uncover the connection system.  
The red base could be used upside down as a stand to position the Vaccine M bottle upside down.  
Twist and remove the green base of the bottle of Vaccine C.



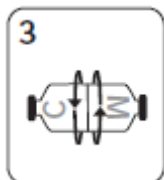
**Step 2**

**Rotate and align** the connection ends of the two bottles until they engage.



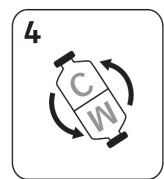
**Step 3**

Now **firmly push** the bottles together until they touch one another completely.  
A click confirms that the bottles are engaged.



**Step 4**

**Twist** the vaccine bottles clockwise to complete the coupling of the two bottles.



**Step 5**

To ensure appropriate mixing, slowly **invert** the locked bottles until the mixture is of uniform colour.