



Product Name: INGELVAC CIRCOFLEX SUSPENSION FOR INJECTION IN PIGS
APVMA Approval No: 63448/135400

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| Label Name: | INGELVAC CIRCOFLEX SUSPENSION FOR INJECTION IN PIGS |
| Signal Headings: | KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY |
| Constituent Statements: | Each 1 mL dose contains: PORCINE CIRCOVIRUS TYPE 2 ORF2 PROTEIN \geq 1.0 RP Also contains: 1mg Carbomer (Adjuvant) |
| Claims: | For active immunisation of pigs from two weeks of age and older as an aid in the prevention and control of diseases associated with porcine circovirus type 2. This vaccine has been demonstrated safe in pregnant and lactating sows. |
| Net Contents: | 100mL 10mL 250mL 50mL |
| Directions for Use: | |
| Restrains: | |
| Contraindications: | |
| Precautions: | Interaction: No information is available on the safety and efficacy of the concurrent use of this vaccine with any other products except with Boehringer Ingelheim's Ingelvac MycoFLEX |
| Side Effects: | A mild and transient hyperthermia very commonly occurs on the day of vaccination. |

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| <p>Dosage and Administration:</p> | <p>SHAKE WELL BEFORE USE and use immediately. Use the entire contents after broaching the container. Administer a single 1 mL dose intramuscularly, irrespective of bodyweight.</p> <p>When mixed with Ingelvac MycoFLEX: Vaccinate only pigs from 3 weeks of age. Use the same volumes of Ingelvac CircoFLEX and Ingelvac MycoFLEX.</p> <p>When mixing using conventional bottles: Use a pre-sterilised transfer needle. Pre-sterilised transfer needles are commonly available via medical equipment suppliers. To ensure correct mixing follow the steps as described below: Connect one end of the transfer needle to the vaccine bottle of Ingelvac MycoFLEX. 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 the empty vaccine bottle of Ingelvac CircoFLEX. To ensure appropriate mixing of the vaccines, gently shake the vaccine bottle of Ingelvac MycoFLEX until the mixture is of uniform orange to reddish colour.</p> <p>When using TwistPak bottles: 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 to position the bottle upside down. Twist and remove the green base of the bottle of Ingelvac CircoFLEX. Step 2: Rotate and align the connection ends of the two bottles until they engage. Step 3: Firmly push the two 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.</p> <p>For both bottle types: During vaccination the uniformity of the coloured mixture should be monitored and maintained by continuous agitation. 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. Use the entire vaccine mixture immediately after mixing. The package leaflet of Ingelvac MycoFLEX should also be consulted before the administration of the mixed product.</p> <p>This section contains file attachment.</p> |
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| <p>General Directions:</p> | <p>Caution: avoid carcass damage</p> <ol style="list-style-type: none"> 1. Sterilise all injection apparatus by boiling before use. Avoid use of strong disinfectants on apparatus. 2. Maintain cleanliness at all times. 3. Keep needles sharp and clean. Replace frequently. 4. Use needles of appropriate gauge and length. 5. As far as possible, avoid injection of animals during wet weather or under dusty conditions. 6. This product should be injected only into the muscle tissue. |
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| <p>Withholding Periods:</p> | <p>Zero (0) days</p> |
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| Trade Advice: | EXPORT SLAUGHTER INTERVAL (ESI): Zero (0) days |
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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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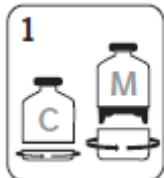
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| Disposal: | Dispose of container by wrapping in paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container. |
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| Storage: | 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.

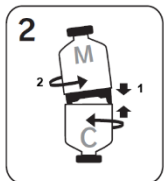


To ensure correct mixing follow the steps as described below:



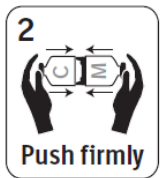
Step 1

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.



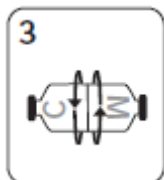
Step 2

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



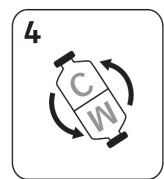
Step 3

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.