SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac MycoFLEX suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
Mycoplasma hyopneumoniae, Strain J, inactivated: ≥ 1 RP*

*Relative potency (ELISA test) by comparison with a reference vaccine.

Adjuvant:
Carbomer:1 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Water for injections

Clear to slightly opalescent, pink to brown suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (fattening pigs or future breeders until first reproductive service).

3.2 Indications for use for each target species

For active immunisation of pigs from 3 weeks of age to reduce lung lesions following infection with *Mycoplasma hyopneumoniae*.

Onset of immunity: 2 weeks post vaccination.

Duration of immunity: 26 weeks.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Anaphylaxis[1] Injection site swelling[2] Injection site reddening[3] Elevated temperature[4]

1 Should be treated symptomatically (e.g., epinephrine)

2 Transient, up to 4 cm in diameter, may last up to 5 days.

3 Observed only in association with the injection site swelling.

4 Mean increase of 0.8 °C, lasting up to 20 hours after vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Boehringer Ingelheim's Ingelvac CircoFLEX and administered at one injection site.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

3.9 Administration routes and dosage

Intramuscular use.
Single injection of one dose (1 ml), preferably in the neck of pigs from 3 weeks of age.
Shake well before use.
Avoid introduction of contamination during use.
Avoid multiple broaching.
Vaccine devices should be used in accordance with the device instructions provided by the manufacturer. After correct handling in accordance with the mixing instructions no leakage should occur. In case of any leakage or incorrect handling of the product the bottle should be discarded.

Use equipment that prevents flush back of the veterinary medicinal product.

When mixed with Ingelvac CircoFLEX:
- Vaccinate only pigs from 3 weeks of age.

When mixed with Ingelvac CircoFLEX the following equipment should be used:
- Use the same volumes of Ingelvac CircoFLEX and Ingelvac MycoFLEX.
- Use a pre-sterilized transfer needle. Pre-sterilized transfer needles (CE certified) are commonly available via medical equipment suppliers.

To ensure correct mixing follow the steps as described below:
1. Connect one end of the transfer needle to the vaccine bottle of Ingelvac MycoFLEX.
2. 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 and discard transfer needle and empty vaccine bottle of Ingelvac CircoFLEX.
3. 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. During vaccination the uniformity of the coloured mixture should be monitored and maintained by continuous agitation.
4. 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.

To ensure correct mixing with the TwistPak bottles follow the steps as described below:

1. **Twist and remove** the red base of the bottle of Ingelvac MycoFLEX to uncover the connection system. The red base could be used upside down as a stand to position of the Ingelvac MycoFLEX bottle upside down.

Twist and remove the green base of the Ingelvac CircoFLEX bottle.

2. **Rotate and align** the connection ends of the two bottles until they engage.
3. **Firmly push** the bottles together until they touch one another completely.

   A click confirms that the bottles are engaged.
4. **Twist** the two vaccine bottles clockwise to complete the coupling of both bottles.
5. To ensure appropriate mixing, slowly **invert** the locked bottles until the mixture is of uniform orange to reddish colour. During vaccination, the uniformity of the coloured mixture should be monitored and maintained by continuous agitation.
6. 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. Any unused mixture or waste material should be disposed of in accordance with local requirements.

The package leaflet of Ingelvac CircoFLEX should also be consulted before the administration of the mixed product.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Following the administration of a 4-fold overdose of vaccine no adverse events other than those described under section 3.6 have been observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB13

This vaccine is designed to stimulate the development of an active immune response to *Mycoplasma hyopneumoniae* in pigs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except with Boehringer Ingelheim´s Ingelvac CircoFLEX.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses) or HDPE TwistPak bottles of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses). Each bottle is closed with a chlorobutyl stopper and lacquered aluminium seal.

Cardboard box of either 1 or 12 bottles.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 61700/5052
Vm 61700/3058

8. DATE OF FIRST AUTHORISATION

04 Aug 2009

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 23 October 2025